UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)
☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

☒ For the fiscal year ended December 31, 2023

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 333-269188

Chromocell Therapeutics Corporation
(Exact name of registrant as specified in its charter)

Delaware	**86-3335449**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4400 Route 9 South, Suite 1000
Freehold, NJ 07728
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(877) 265-8266**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol	Name of each exchange on which registered:
Common Stock, $0.0001 par value	**CHRO**	**The NYSE American LLC**

Securities registered pursuant to Section 12(g) of the Act:

None
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☒

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The registrant completed the initial public offering of its common stock on February 21, 2024. Accordingly, there was no public market for the registrant's common stock as of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter.

The registrant had 5,877,835 shares of its common stock outstanding as of April 15, 2024.

References in this Annual Report on Form 10-K to the “Company,” “Chromocell,” “we,” “us,” or “our” mean Chromocell Therapeutics Corporation unless otherwise expressly stated or the context indicates otherwise.

Documents Incorporated By Reference: None.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Report") contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include information concerning our strategy, future operations, future financial position, future revenue, projected expenses, prospects and plans and objectives of management. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict, "project," "seek," "should," "target," "will," "would" or similar expressions and the negatives of those terms.

Forward-looking statements contained in this Report include, but are not limited to, statements about the following:

- the initiation, timing, progress and results of preclinical and clinical trials for CC8464, CT2000 and any other compounds, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing, scope or results of regulatory filings and approvals, including timing of final U.S. Food and Drug Administration ("FDA") marketing and other regulatory approval of CC8464 and CT2000;
- our ability to achieve certain accelerated or orphan drug designations from the FDA;
- our estimates regarding the potential market opportunity for CC8464 and CT2000;
- our research and development programs for our lead compounds, CC8464 and CT2000;
- our plans and ability to successfully develop and commercialize future compounds, including CC8464 and CT2000;
- our ability to identify and develop new compounds;
- our ability to identify, recruit and retain key personnel;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the implementation of our business model, strategic plans for our business, lead compounds and technology;
- the scalability and commercial viability of our proprietary manufacturing methods and processes;
- the rate and degree of market acceptance and clinical utility of our lead and any other future compounds;
- our competitive position;
- our intellectual property position and our ability to protect our intellectual property and enforce our intellectual property rights;
- our financial performance;
- developments and projections relating to our competitors and our industry;
- our ability to establish and maintain collaborations or obtain additional funding;
- our expectations related to the use of proceeds from the offering of the shares registered in the Company's initial public offering (the "IPO");
- our estimates regarding expenses, future revenue, capital requirements and needs for or ability to obtain additional financing;
- the impact of laws and regulations; and
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act").

Forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in " *Risk Factors*" and elsewhere in this Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Report. You should read this Report and the documents that we have filed as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

For discussion of factors that we believe could cause our actual results to differ materially from expected and historical results, see " *Item 1A - Risk Factors*" below. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

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PART I

Item 1. Business

Overview

We are a clinical-stage biotech company focused on developing and commercializing new therapeutics to alleviate pain. Our clinical focus is to selectively target the sodium ion-channel known as “NaV1.7”, which has been genetically validated as a pain receptor in human physiology. A NaV1.7 blocker is a chemical entity that modulates the structure of the sodium-channel in a way to prevent the transmission of pain perception to the central nervous system (“CNS”). Our goal is to develop a novel and proprietary class of NaV blockers that target the body’s peripheral nervous system, target the following indications:

1) Neuropathic pain, with a focus on Erythromelalgia (“EM”), a rare condition characterized primarily by searing pain in the feet and, less commonly, by the hands (extremities) and idiopathic small fiber neuropathy (“iSFN”), a painful condition with associated nerve damage in the hands and feet. Neither EM nor iSFN have currently approved treatments.
2) Acute and chronic eye pain resulting from disease, surgery or trauma.

According to Mordor Intelligence, the global pain management market was valued at approximately $67 billion in 2021, and it is expected to have revenues of $89 billion in 2027, with a compound annual growth rate of 4.65% over the forecast period. Also, according to Mordor Intelligence, the United States has the largest market for pain management pharmaceuticals and Asia-Pacific is the region showing the strongest growth. North America holds the largest share in the pain management market, with the United States being the most significant contributor to its revenue. According to data published by the Centers for Disease Control and Prevention (“CDC”), in 2019, 20.4% of adults had chronic pain, and 7.4% of adults had chronic pain that had limited work and daily activities frequently. Additionally, according to the CDC, chronic pain increased with age, and the highest level was reported in patients aged 65 years and above. The prescription pain management market in the United States is still largely dominated by opioid analgesics. Opioid analgesics decrease the perception of pain by stimulating a range of opioid receptors that modulate pain signals. The most widely used opioid analgesics, including morphine, fentanyl and hydromorphone, act primarily through the activation of mu opioid receptors in the CNS. However, because of the wide distribution of mu opioid receptors throughout the brain, morphine and other mu opioid analgesics also trigger a characteristic pattern of adverse side effects, in particular euphoria and severe abuse and addiction.

The global pain market reflects total revenues of drugs mitigating different types of pain, such as backpain, osteoarthritis, post-operative pain and various orphan diseases with pain symptoms. We have formally launched two programs developing pain treatment therapeutics, both based on the same proprietary molecule, as follows:

1. Neuropathic Pain: CC8464, is being developed to address certain types of neuropathic pain. The chemical characteristics of CC8464 restrict its entry into the CNS and limit its effect to the NaV1.7 receptors in the peripheral nervous system, which consists of the nerves outside the brain and spinal cord. Activation of other receptors in the CNS can result in side effects, including addiction and other centrally mediated adverse effects. Since CC8464 is designed to not penetrate the CNS it is highly unlikely to produce CNS mediated side effects including euphoria or addiction. Based on its characteristics, preclinical studies (described below) and the Phase 1 studies we have completed to date, we believe that CC8464, if approved, could become an attractive option for both patients and physicians as a treatment for moderate-to-severe pain in EM and iSFN.

The therapeutic benefit of CC8464 will, among other factors, be determined by its potency and selectivity. The potency reflects the compound's effect in blocking the NaV1.7 channel. The selectivity is the absence of effects in blocking other, similar channels (e.g. NaV1.5) that could cause undesirable side effects. We conducted *in vitro* and *in vivo* studies described in more detail below that showed both a high potency and selectivity of CC8464. While positive results of *in vitro* and *in vivo* studies do not necessarily translate into human studies, we believe that the consistency of results in various *in vivo* models (rat, mouse, mini-pig) supports the projection of a positive outcome in clinical studies.

CC8464 is a potent inhibitor of the inactivated state of the human NaV1.7. We measured with our electrophysiology equipment the difference in affinity between cells with and without CC8464 added *in vitro*. The results showed that the compound preferentially inhibits the inactivated state of the channel with 1000-fold higher affinity as compared to the resting state. Injury or chronic inflammation is associated with persistent neuronal depolarization that shifts NaV1.7 channels to the inactivated state. Therefore, CC8464 may preferentially affect injured or inflamed tissues while having minimal effect on the hNaV1.7 channels in uninjured/healthy tissues. CC8464 displays high target selectivity and a favorable in vitro cardiac safety profile (*in vitro* electrophysiology experiments where we measured differences between cells with and without CC8464 added showed a>1,000-fold selectivity for human NaV1.7 over human NaV1.5, hERG and human CaV1.2 ion channel receptors). Further, a canine cardiovascular and respiratory *in vivo* study where vital signs of canines were monitored after administering CC8464 showed no adverse findings. CC8464 demonstrated minimal activity against a broad array of potential targets and off-targets with only one confirmed IC50 less than 10 μM (κ-opioid receptor agonist). At predicted therapeutic doses, there is >100-fold selectivity for hNaV1.7 over the κ-opioid receptor. In vivo, CC8464 selectivity may be augmented by a lack of exposure in the central nervous system. In an *in vivo* tissue distribution study in rats all of the tissues in the central nervous system did not have measurable concentrations of CC8464-derived radioactivity at any time point post-dose. Behavioral effects potentially attributable to the CNS have not been observed in animals. There were no CC8464 related effects on any parameter in the functional observational battery evaluation conducted as a part of the 28-day repeat dose study in rats. In a streptozotocin-induced diabetic neuropathy model, wherein rats self-administered CC8464, there was no increase in intake in up to 8 weeks of dosing. There was no evidence of motor/balance impairments on observational measurements in the foot-fault test, where motoric/balance impairments are monitored *in vivo* after administering CC8464. Also, no immobility or lethargy observations were reported in cage side observations in any of the nonclinical efficacy studies performed. CC8464 has shown statistically significant efficacy in reversing pain in several nonclinical neuropathic and inflammation induced pain models, where motoric/balance impairments were monitored *in vivo* by comparing results from animal cohorts and preventing the emergence of neuropathic pain in neuropathic pain models. CC8464 has been shown to reverse thermal and mechanical hyperalgesia, spontaneous pain and tactile allodynia in these models. The reversal of hyperalgesia endpoints follows the pharmacokinetics of CC8464 in plasma. The reversal of tactile allodynia in rats was more gradual and disassociated from the pharmacokinetics, but the therapeutic effect is comparable to the effect on hyperalgesia endpoints and is sustained for some time after the cessation of treatment. There was no tachyphylaxis observed on efficacy parameters after repeated dose administration in the partial sciatic nerve ligation and streptozotocin-induced diabetic neuropathy models.

A total of 207 healthy subjects have been dosed in four Phase 1 studies (CC8464-1001, CC8464-1002, CC8464-1003, and 1807-CL-0102) with study treatment. The studies were sponsored by Chromocell Corporation, a Delaware corporation ("Chromocell Holdings"). A Phase 1 study investigating safety, tolerability and pharmacokinetics of single and multiple ascending doses of CC8464 in healthy volunteers has been completed (Study Protocol CC8464-1001). CC8464-1002 and CC8464-1003 were relative bioavailability studies in healthy volunteers to support new formulations. CC8464 was, in general, well tolerated in these Phase 1 studies. Skin rash, the only clinically relevant safety finding, was seen in a total of six (6) out of the 159 subjects dosed with CC8464 in these Phase 1 studies (CC8464-1001, CC8464-1002, CC8464-1003).

Following clinical completion of the studies CC8464-1001, CC8464-1002, and CC8464-1003, a drug-drug interaction (DDI) study 1807-CL-0102 was initiated to examine the effect of CC8464 on the PK and Pharmacodynamics (PD) of warfarin, a CYP2C9 substrate. This was the first study with a BID dosing regimen (CC8464 400 mg BID daily for two weeks) which had greater accumulation than expected. Thirteen out of eighteen (13/18) subjects dosed with CC8464 reported rash in this open label drug-drug interaction study. Clinical presentation and resolution of the rashes reported in study 1807-CL-0102 were consistent with the rash cases from CC8464-1001 except for a single case of a skin reaction requiring IV corticosteroid therapy (SAE). All reported skin rashes in study 1807-CL-0102 resolved within days of treatment discontinuation without sequalae.

Overview of Studies – CC8464 for Neuropathic Pain

Study ID/ Location	**Study Title**	**Study Design**	**Dosing Regimen**	**Study Population**	**FPFV***	**Planned Enrollment**	**Subject exposure**
CC8464-1001 (USA)	A Randomized, Double Blind, Placebo Controlled, Single Ascending Dose and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Oral Doses of CC8464 in Normal Healthy Subjects with Food Effect Assessment	SAD/MAD	SAD: 30, 120, 300, 600, 1200, 1800, or 2400 mg QD on Day 1. MAD: 120, 300, 600, 1200, 1800 or 2400 mg QD on Days 1-14.	Healthy Volunteers	September 13, 2016	206	125
CC8464-1002 (USA)	A Phase 1 Crossover Study to Assess the Relative Bioavailability of CC8464 following a Single Dose of Melt Granulation Capsule Compared to a Single Dose of Encapsulated Suspension in Normal Healthy Subjects with a Food Effect Assessment	Cross-over	200 mg Melt Granulation Capsule (fed and fasted) vs 200 mg Suspension Capsule (fasted)	Healthy Volunteers	July 31, 2017	24	24
CC8464-1003 (USA)	A Single-Dose, Open-Label, Five-Period, Randomized, Crossover Study to Compare the Relative Bioavailability and Dose Proportionality Between Two Formulations and 3 Dosage Strengths of CC8464 in Healthy Volunteers	Cross-over	50 mg, 100 mg and 400 mg of CC8464 Melt Granulation Tablet (Fed and Fasted) vs 2x200 mg of Melt Granulation Capsules	Healthy Volunteers	February 5, 2018	40	40
1807-CL-0102 (USA)	A Phase 1 Study to Evaluate the Effect of Multiple Doses of CC8464 (ASP1807) on the Pharmacokinetics and Pharmacodynamics of Warfarin in Healthy Subjects	Drug-Drug Interaction	Single doses of 5mg Warfarin tablets will be taken on days 1 and 15. 400mg of CC8464 BID will begin on Day 8 and continue until 6 days after the second dose of Warfarin is taken, for a total of 14 days	Healthy Volunteers	May 16, 2018	18	18

* FPFV = first patient first visit

The results showed that CC8464 has a good overall tolerability and demonstrated no liver or renal toxicity, no central nervous system changes and no cardiovascular findings, but the results showed that CC8464 may cause rashes in certain patients. The occurrence of rashes is not uncommon in the class of molecules to which CC8464 belongs and the rashes were resolved in all cases with topical steroids and/or topical antihistamines (with the exception of one patient requiring systemic steroids).

As a result of the potential for rashes, following discussions with the U.S. Food and Drug Administration ("FDA"), we decided to launch a slow dose escalation study to further evaluate the incidence of rashes. By titrating the dose over nine weeks, we anticipate that we will reduce or eliminate this side effect. We expect that the slow dose escalation study will also help determine the need for dose escalation in the final treatment regime. Even though the FDA has in the past approved drugs that listed rashes as a potential side effect, we do not know if CC8464 will be approved by the FDA (or any foreign authority).

We anticipate that the dose escalation will enroll the first patient dosing in the third quarter of 2024. The dose escalation trial will enroll approximately 20 healthy volunteers who will receive CC8464 over a period of approximately nine weeks, with the dose escalation study expected to take approximately nine months in total. We anticipate that the slower dose escalation will decrease the likelihood of drug-related skin reactions. The primary endpoint of the dose escalation trail will be safety and tolerability of the slower dose titration; however, we will also be measuring blood concentrations of CC8464, which will allow us to better understand the pharmacokinetics of CC8464. Even if it is ultimately determined that we will need an escalation period for chronic pain treatment therapy, which patients could well take for the remainder of their lives, we do not believe the dose escalation approach is consequential.

We are conducting the escalation trial in Australia to avail ourselves of a 43.5% tax credit for clinical expenses incurred in Australia. The location of the proof-of-concept ("POC") plan has not been determined at this time, and we will determine the ultimate location based on availability of facilities and patient population, costs, tax credits and centers of excellence in the respective fields (EM or iSFN).

We are currently working on the development of the Phase 2a POC plan and expect to launch the Phase 2a POC study in 2025 to assess the potential efficacy of CC8464 in EM and iSFN patients. Both EM and iSFN are orphan indications for which we plan to apply for orphan drug designations. The orphan indication may decrease the scope of the ultimate development program that is necessary for approval and is associated with a marketing exclusivity period from the FDA along with some tax advantages.

Though the Phase 2a POC study design has not yet been completed, we expect that the study will take approximately twelve months after it is initiated. We will be using a cross-over design which has the advantage of increasing the study power while keeping the number of patients relatively low. Each patient will be exposed to both placebo and CC8464 during the two cross-over phases of the trial but neither the investigators nor the patients will know when they are receiving active drug or placebo. The primary endpoint will be the amount of pain experienced from EM or iSFN with secondary endpoints including other measurements like pain relief, time to onset of the flare and neuropathy scores. The final design may change based on feedback from the FDA or information learned during the dose escalation trial.

The potential population for EM in the United States is estimated to be between 5,000 and 50,000 patients and the potential population for iSFN in the United States is estimated to be between 20,000 and 80,000 patients. In both instances, we expect patients would potentially take our drug for the remainder of their lives, and given the lack of good therapeutic alternatives, we expect to have a robust, ongoing, and durable market.

The Phase 2a results will have significance beyond EM and iSFN and provide important insights about NaV1.7 as a potential target to find novel pain medications as an alternative to opioids, the continuing primary standard of care in analgesics. We believe that positive results from the Phase 2a study could not only act as support for CC8464's potential in EM and iSFN but may also provide guidance of its potential for other indications of peripheral neuropathic pain.

2. Eye Pain: Based on the same proprietary molecule as CC8464, our newly launched program, titled CT2000, is for the potential treatment of both acute and chronic eye pain. NaV1.7 receptor is present on the cornea, making it a viable biological target for treating eye pain. Eye pain may occur with various conditions, including severe dry eye disease, trauma and surgery. Existing therapies for eye pain (such as steroids, topical non-steroidal anti-inflammatory agents, lubricants, local anesthetics) are limited in their effectiveness and/or limited in the duration that they may be prescribed because of safety issues. We intend to explore the viability of developing CT2000 as a topical agent for the relief of eye pain. A potential advantage of this approach is that topical administration of CT2000 is unlikely to lead to any hypersensitivity or skin reactions, like what was noted with systemic administration of CC8464, because the systemic absorption from a topical administration would be extremely limited. We have commenced development of a topical ophthalmic formulation of CT2000 that would initially be utilized for toxicology and in vivo studies and then followed by a POC trial in patients suffering from various conditions, including severe dry eye disease, trauma and surgery. We expect the trials for this ophthalmic formulation of CT2000 to start in the fourth quarter of 2024.

Current options for the treatment of ocular pain center on the use of corticosteroids and non-steroidal anti-inflammatory drug ("NSAID") based therapeutics. These options suffer from sight-threatening complications such as Glaucoma and corneal melting, thus there is a large unmet need for other approaches. We estimate that there are approximately 5 million cases of corneal abrasions per year in the United States. In addition, other potential indications associated with eye pain include:

- severe dry eye,
- side effects from photorefractive keratectomy (PRK) and pterygium surgery,
- second eye cataract surgery,
- neuropathic corneal pain, and
- severe uveitis and severe iritis/scleritis.

As the NaV1.7 receptor is present on the cornea, making it a viable biological target for treating eye pain, we believe that we have a sound scientific basis for our ability to treat a multitude of eye pain indications. We are in the process of formulating CT2000 eye drops and expect to move into animal toxicity studies in the second half of 2024. From there, we intend to move into POC studies in humans in Australia.

We may further expand our pipeline with other internal or external compounds in the future, but all other internally discovered compounds are pre-clinical and no commercial discussions about in-licensing have been initiated to date, other than as disclosed herein with respect to the licensing of the Diclofenac Spray Formulation (as defined below), Rizatriptan Spray Formulation (as defined below) and Ondansetron Spray Formulation (as defined below and collectively, the "Spray Formulations").

Our Strategy

We are a clinical-stage pharmaceutical company focused on non-opioid pain blockers in the NaV space. Our development programs are initially designed to address the underlying condition and mitigate the pain associated with neuropathic pain and eye pain. The key elements of our strategy to achieve our mission are:

- ***Advance the development of CC8464 towards FDA approval for treating EM and iSFN.*** Based on its pre-clinical profile, the target validation and trends seen with other NaV1.7 blockers in clinical studies, if approved by the FDA, we believe that CC8464 has the potential to become a drug for treatment of EM and iSFN patients, potentially delivering meaningful clinical benefits over the currently available standard of care.

- ***Develop CT2000 for the treatment of eye pain.*** According to a presentation at the Association for Research in Vision and Ophthalmology, with the abstract published in the publication, Investigative Ophthalmology and Visual Science in June 2020, NaV1.7 receptor is present on the cornea and as such, is a viable biological target for treating eye pain. We have commenced development of a topical ophthalmic formulation of CT2000 that will be evaluated for ophthalmic toxicology and then followed by a POC trial in patients. We expect the trials for this ophthalmic formulation of CT2000 to start in 2025.

- ***Leverage our differentiated research and discovery approach to expand our pipeline.*** We plan to build a pipeline of potential pain blockers acting against sodium-channels related to NaV1.7. Pain modulation is complex, and a multitude of physiological mechanisms are involved in transmitting pain signals. Other than NaV1.7, we believe that several related sodium channels, e.g., NaV1.8 or NaV1.6, may be involved in pain sensation. While NaV1.7 is the most validated pain receptor, we believe that blockers against other sodium channels may complement CC8464 and CT2000 as our primary pain blocking candidates.

- ***Build a leading, fully integrated pharmaceutical company to maximize the clinical impact and value of our pipeline and deliver value to stockholders.*** We plan to build an experienced team to rapidly advance compounds in a capital-efficient manner. We intend to retain the commercialization rights to our lead compounds; however, we may opportunistically enter into strategic collaborations in certain geographic or clinical settings to maximize the value of our pipeline.

While we currently do not have strategy and development plans for the Spray Formulations licensed from Benuvia Operations LLC ("Benuvia"), beginning in the fourth quarter of 2024, we will consider developing clinical programs for each of the Spray Formulations, determine the labelling strategy that would be obtained from completion of these programs and evaluate the requirements for bringing each of the Spray Formulations to market. We anticipate bringing the Spray Formulations to market through the FDA 505(b)(2) regulatory pathway for new drug applications; however, the exact details will require further consultation with the FDA.

Our Lead Drug Candidates and Pipeline

We intend to focus our efforts on the development of CC8464 and CT2000, our lead compounds, towards approval in the United States and other jurisdictions. While CC8464 and CT2000 are the focus of our efforts, we may also allocate future resources towards the discovery and development of other compounds that could potentially treat pain.

CC8464's FDA Orphan Drug Designation

We are considering submitting a request to the FDA for Orphan Drug Designation for EM and iSFN, which could lead to approval for such designation. Orphan Drug Designation provides for a seven-year window of exclusivity and potential 25% tax credit on qualified clinical trials, as well as reduced FDA review periods and regulatory fees. We may apply for similar designations in additional jurisdictions, including India, Japan and Mexico, as well as additional regulatory classifications, such as FDA Breakthrough Therapy designation, that confer an advantage during development. As of the date of this Report, we have not submitted an application for orphan drug designation for CC8464.

CC8464 and CT2000 Manufacturing

We plan to manufacture the clinical and eventual commercial supply through Clinical Manufacturing Organizations ("CMOs") in the U.S. and potentially other jurisdictions. We do not produce drug substances in house. External CMOs have produced enough CC8464 drug substance to conduct the dose escalation trial, prepare the eye pain formulation, conduct the eye pain toxicology trial and potentially, to conducts the Phase 2 proof of concept for neuropathic pain and acute and chronic eye pain.

We have rights to two proprietary methods to produce CC8464. We have not yet decided which production process we will use for subsequent clinical trials and eventual commercial supply, but both appear suitable for further use and optimization. Both manufacturing processes employ common methods of organic synthesis used in the production drug substance. We do not intend to file patents for these processes but will keep the detailed protocols (e.g., the selected crystallization solvent or the particular salt) as trade secrets.

The Company is developing the formulation for the eye drops associated with the eye pain treatment therapy, after which, we will determine our manufacturing strategy. We expect to pursue a similar strategy to have CT2000 manufactured by CMOs.

Benuvia Spray Formulations

On December 23, 2023, we entered into an exclusive licensing agreement (the "Benuvia License Agreement") with Benuvia for the Spray Formulations, diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The sublingual formulation of a Diclofenac spray for the treatment of acute pain (the "Diclofenac Spray Formulation") is patented and has started clinical development in human volunteers. Preliminary pharmacokinetics suggest that this formulation may have a faster onset of action than oral Diclofenac tablets. Diclofenac is an NSAID that is also marketed under additional brand names including Voltaren and Cataflam in its pill form. A single Phase 1 trial of the Diclofenac Spray Formulation was completed in 24 healthy volunteers wherein a single dose of 50mg diclofenac-potassium was compared to 25 mg of Diclofenac Spray Formulation. In this trial, the blood plasma concentrations of Diclofenac rose more quickly with the Diclofenac Spray Formulation than with the diclofenac administered orally by approximately 15 minutes. This suggests that the Diclofenac Spray Formulation may have a faster onset of analgesia; however, additional trials may be needed to confirm this effect. Additionally, the initial pharmacokinetic study demonstrated that a 25mg dose of Diclofenac Spray Formulation resulted in lower systemic exposure to Diclofenac than the oral dose of 50mg diclofenac-potassium which means that an additional Phase I pharmacokinetic study exploring additional higher doses of the sublingual diclofenac spray will likely be necessary to determine the appropriate dose.

Rizatriptan, whose brand name is Maxalt, is used for the acute treatment of migraines as a pill. By a number of clinical measures it is thought to be superior to Sumatriptan. Both Rizatriptan and Sumatriptan belong to a family of tryptamine-based medications named "triptans" that work as serotonin 1A receptor (or 5-HT1A-receptor) agonists and are indicated for the treatment of migraine. An intranasal spray formulation of Rizatriptan (the "Rizatriptan Spray Formulation") may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea as a result of the migraine headache. According to a study that was reported in 2001, Rizatriptan has a higher bioavailability and a more rapid onset of action which may be responsible for better results in resolving migraines as well as better results in patients reporting that they are "pain free" after 2 hours. Both Sumatriptan and Rizatriptan are competitors for the same indication, though neither are widely marketed because they are generic drugs.

Ondansetron is an anti-emetic that is available in oral and intravenous form. An Ondansetron sublingual spray formulation (the "Ondansetron Spray Formulation") may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations.

While we currently do not have strategy and development plans for the Spray Formulations licensed from Benuvia, beginning in the second half of 2024, we plan to develop clinical plans for each of the Spray Formulations, determine the labelling strategy that would be obtained from completion of these programs and evaluate the regulatory requirements for bringing each of the Spray Formulations to market. We anticipate bringing the Spray Formulations to market through the FDA 505(b)(2) regulatory pathway for new drug applications; however, the exact details will require further consultation.

Intellectual Property

Protection of our intellectual property is an important part of our business. We seek patent protection in the United States and in other countries for our inventions and discoveries, and we develop and protect our key know-how and trade secrets relating to our platform technology and the products we are developing using our platform.

We have adopted a strategy of seeking patent protection in the United States and in other jurisdictions globally that we deem appropriate with respect to certain of our technologies relating to our products and process. As of February 21, 2024, we have received an issued patent from the United States Patent and Trademark Office ("USPTO") directed to the composition of matter and use of CC8464. We have also obtained patents in France, Japan, India and other smaller markets (Mexico, Israel and South Korea). Our U.S. patent for CC8464 will expire in 2035. The Company owns the patent and has not licensed any portion to third parties. In addition, we have an additional pending patent application in India. While the eventual issuance of a patent in India cannot be guaranteed, we believe that we have a good chance to obtain comprehensive composition of matter protection for CC8464 during 2024.

We are preparing our patent protection strategy with respect to CT2000, but we expect to apply for patents across all major international jurisdictions beyond and including the United States.

The Diclofenac Spray Formulation is covered by U.S. Patent 9,855,234. The patent was issued in January 2018 to Benuvia and is a composition-of-matter patent that will expire, barring a patent term adjustment, in April 2036. The patent coverage applies to the United States. The Ondansetron Spray Formulation is covered by U.S. Patent 9,566,233 and U.S. Patent 10,172,833. Both patents are composition-of-matter patents that will expire, barring a patent term adjustment, in May 2034 and August 2036, respectively. The patent coverages apply to the United States. The U.S. and international patents relating to the Rizatriptan Spray Formulation have either expired or have been abandoned.

In addition to patents and licenses, we rely on trade secrets and know-how to develop and maintain technologies and methods that provide us a meaningful competitive advantage. However, trade secrets can be difficult to defend and maintain. We seek to protect our proprietary technology and processes, and maintain ownership of certain technologies, in part, through confidentiality agreements and invention assignment agreements with our employees, consultants and commercial partners.

Our Competition

The biotechnology and pharmaceutical industries are highly competitive. Several pharmaceutical companies that are developing molecules that modulate NaV (including NaV1.7 and NaV1.8) activities and therefore have the potential to mitigate EM, iSFN and eye pain. These companies and new entrants may potentially compete with our products in the future with novel delivery technologies. Competition in this space will remain strong and we do not know if we will be successful in obtaining orphan designation from the FDA for CC8464, encounter challenges to our issued patents and continue to advance CC8464 and C2000 through clinical development towards approval.

In connection with the IPO, we entered into a side letter with Chromocell Holdings, pursuant to which Chromocell Holdings agreed not to (i) directly or indirectly engage in the business of owning, licensing, developing, marketing, manufacturing, producing, selling or distributing products, technologies, therapies, or services in any way related to our business, including all patents, pre-clinical and Phase I study results and data, and trade secrets related to the CC8464 compound, transferred by Chromocell Holdings to us further to the that certain Contribution Agreement (the "Contribution Agreement") with Chromocell Holdings. Pursuant to the Contribution Agreement, effective July 12, 2022 (the "Contribution Date"), (ii) directly or indirectly, hire, engage or employ (as an employee, consultant or otherwise) any of our employees; provided that Chromocell Holdings shall not, directly or indirectly, prevent any of our employees from serving on the board of directors of Chromocell Holdings, and (iii) through any director or officer of Chromocell Holdings, directly or indirectly, solicit for employment or the engagement of services of any of our employees or induce or attempt to induce any of our employees to leave his or her employment with us, or in any way intentionally interfere with the employment relationship between any of our employees and us, for the purpose of employing or engaging the services of such employee or soliciting such employee to become an employee or consultant of Chromocell Holdings or any other person.

Our Facilities

Our office is located at 4400 Route 9 South, Suite 1000, Freehold, NJ 07728. We are considering lab options commensurate with the start of the Phase II trials and dose escalation study.

Employees and Human Capital Resources

As of April 10, 2024, we had four full-time employees and four consultants on a part-time basis. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

In addition, we have a three person Scientific Advisory Board led by Dr. Stephen Waxman, who is the Bridget M. Flaherty Professor of Neurology and of Neuroscience and the Director of the Center for Neuroscience and Regeneration Medicine at Yale University School of Medicine.

Legal Proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputation harm, and other factors.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as outside the United States, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and biologics. We, along with our vendors, Clinical Research Organizations ("CRO"), clinical investigators, clinical trial sites and contract manufacturing organizations, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek marketing approval of compounds. The process of obtaining regulatory approvals of drugs and biologics and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States where we are initially focusing our drug commercialization, we believe compounds, as small molecule drugs, would be regulated as new drugs rather than biologics. The FDA regulates new drug products under the Federal Food, Drug, and Cosmetic Act, as amended (the "FDCA") and its implementing regulations. New drug products are also subject to other federal, state and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other regulatory requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for proposed or ongoing studies, suspension or revocation of approvals, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

Compounds must be approved for therapeutic indications by the FDA before they may be marketed in the United States. For new drug products regulated under the FDCA, a sponsor must submit a U.S. New Drug Application ("NDA") to the FDA for review and approval. The NDA review and approval process may take multiple years and involves the following steps:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with Good Laboratory Practice ("GLP") requirements;

- completion of the manufacture, under current Good Manufacturing Practices ("cGMP") conditions of the drug substance, drug product, and labeling and packaging that the sponsor intends to use in human clinical trials along with required analytical and stability testing;

- submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before clinical trials may begin and must be updated annually and amended when certain changes are made;

- approval by an institutional review board ("IRB") or independent ethics committee ("IEC") at each clinical trial site before each trial may be initiated;

- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, Good Clinical Practice ("GCP") requirements, including informed consent, financial disclosure by investigators and other clinical trial-related regulations, to establish maximum tolerable dose and efficacy of the investigational product for each proposed indication and other condition of use;

- preparation and submission to the FDA of an NDA;

- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;

- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug product's identity, strength, quality and purity;

- satisfactory completion of FDA inspection of select clinical trial sites involved in conducting pivotal studies that generated the data in support of the NDA;

- payment of user fees for FDA review of the NDA; and

- FDA review and approval of the NDA, including of the proposed prescribing information and, where applicable, consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

Preclinical Studies and Clinical Trials for Drugs

Before testing any drug in humans, compound must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of product chemistry, formulation and stability, as well as in vitro and animal studies to assess maximum tolerable dose and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulation and requirements, including GLP requirements under 21 C.F.R. Part 58 and animal testing requirements under the Animal Welfare Act Amendments of 1976 (7 U.S.C. 2131 et seq.). The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND.

An IND is a submission to the FDA under which a sponsor proposes to administer an investigational product to humans. An IND must become effective before the proposed clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes the results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, refuses to allow the IND to take effect until the FDA's concerns and questions have been addressed and/or imposes a full or partial clinical hold. The FDA must notify the sponsor of the grounds for the hold, and any identified deficiencies must be resolved before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A clinical hold can also be imposed once a trial has already begun, thereby halting the trial until the deficiencies articulated by FDA are corrected.

The clinical stage of development involves the administration of the compounds to healthy volunteers or patients under the supervision of qualified investigators, who generally are physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND.

Furthermore, each clinical trial must be reviewed and approved by an IRB or IEC for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable compared to the anticipated benefits. The IRB or IEC also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. The FDA, the IRB or IEC, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than phase 1 investigations, must be submitted within specific timeframes for publication on www.ClinicalTrials.gov, a clinical trials database maintained by the National Institutes of Health.

A sponsor who wishes to conduct a clinical trial outside of the United States are subject to the requirements of the applicable jurisdiction and may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the FDA will nevertheless accept the results of the study in support of an NDA if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- Phase 1 — Phase 1 clinical trials involve initial introduction of the investigational product in a limited population of healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2 — Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the drug's potential efficacy, to determine the optimal dosages and dosing schedule, and to identify possible adverse side effects and safety risks.

- Phase 3 — Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy, and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended, with the other available evidence, to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling. Generally, two adequate and well-controlled phase 3 trials are required by the FDA for approval of an NDA. Under certain circumstances, FDA can conclude that one adequate and well-controlled clinical investigation plus confirmatory evidence is sufficient to establish effectiveness.

Post-approval trials, sometimes referred to as phase 4 clinical trials or post-marketing studies, may be conducted after initial marketing approval. These trials are used to gain additional evidence from the treatment of study subjects in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting, or in some cases to confirm clinical benefit. In certain instances, the FDA may mandate the performance of phase 4 clinical trials as a condition of NDA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk for human volunteers, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the compound and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the compound and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the compound does not undergo unacceptable deterioration over its shelf life.

Expanded Access

Expanded access, sometimes called "compassionate use," is the use of investigational products outside of controlled clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational products under an IND by the sponsor or the treating physician for treatment purposes on a case-by-case basis for the following groups: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or treatment IND.

A clinical trial sponsor is not obligated under the law to provide expanded access to its investigational product. However, if a sponsor decides to make its investigational product available for expanded access, FDA reviews each request for expanded access and determines if treatment may proceed. Expanded access may be appropriate when all of the following criteria apply: the patient has a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context of the disease or condition to be treated; and providing the investigational product for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides an additional mechanism for patients with a life-threatening condition who have exhausted approved treatments and are unable to participate in clinical trials to access certain investigational products that have completed a phase 1 clinical trial, are the subject of an active IND, and are undergoing investigation in a clinical trial that is intended to form the primary basis of a claim of effectiveness in support of FDA approval. Unlike the expanded access framework described above, the Right to Try Act does not require FDA to review or approve requests for use of the investigational product, although the law requires sponsors to report annually to the FDA on use of the pathway and require the FDA to post certain annual summaries. There is no obligation for a sponsor to make its investigational products available to eligible patients under the Right to Try Act.

Under the 21st Century Cures Act, the manufacturer or distributor of one or more investigational products for the diagnosis, monitoring and treatment of a serious disease or condition must make publicly available their policy for evaluating and responding to requests for expanded access for individual patients. The manufacturer or distributor is required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study, or as applicable, 15 days after the investigational drug receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy. The posting of the expanded access policies by manufacturers and distributors does not serve as a guarantee of access to any specific investigational drug by any individual patient, but the sponsor must develop a policy and respond to patient requests according to that policy.

U.S. Marketing Approval for Drugs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA package requesting approval to market the drug product for one or more indications. An NDA is an application to FDA for approval to market a new drug for one or more specified indications and must contain proof of the drug's maximum tolerable dose and efficacy for the requested indication(s). An NDA is required to include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data may come from company-sponsored clinical trials intended to test the maximum tolerable dose and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the maximum tolerable dose and efficacy of the investigational drug, to the satisfaction of the FDA. The FDA must approve an NDA before a drug may be marketed in the United States.

The FDA reviews all submitted NDAs to ensure they are sufficiently complete to permit substantive review before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt, and such decision could include a "refuse-to-file" decision by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the product is safe and effective for the indications sought and whether the facility in which it is manufactured, processed, packaged or held meets standards designed, including cGMP requirements, designed to assure and preserve the product's continued identity, strength, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, as amended (the "PDUFA"), the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA and respond to the applicant, and six months from the filing date of a new molecular entity NDA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, each NDA must be accompanied by a substantial user fee. For fiscal year 2023, the application fee for each application containing clinical data is $3,242,026. PDUFA also imposes an annual program fee for each approved prescription drug, which has been set at $393,933 for fiscal year 2023. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on applications for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy ("REMS") if it believes that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use such as restricted distribution methods, patient registries, special monitoring or other risk-minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides advice and recommendations to FDA as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more select clinical trial sites involved in conducting pivotal studies to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the complete response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the complete response letter, the FDA may require additional clinical or preclinical testing or recommend other actions, such as requests for additional information or clarification, that the applicant might take in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indication(s).

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including phase 4 clinical trials, be conducted to further assess a product's maximum tolerable dose and efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition with either a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States when there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting a marketing application. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its designated orphan use are disclosed by the FDA on its website. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

If a product that has orphan drug designation subsequently receives the first FDA approval for the use for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity from the date of FDA approval during which the FDA may not approve any other applications to market the "same drug" for the same use, except in limited circumstances, such as a subsequent product's showing of "clinical superiority" over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. The FDA defines "same drug" with respect to small molecule drugs as a drug that contains the same active moiety as a previously approved drug and is intended for the same use as the previously approved drug. To demonstrate a drug is "clinically superior" to the previously approved orphan drug, a sponsor must show that the drug provides a significant therapeutic advantage over and above the previously already approved drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care. Since the enactment of the FDA Reauthorization Act of 2017, the FDA publishes clinical superiority findings on its website for those drugs approved on or after August 18, 2017. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if the manufacturer chooses to provide consent to approval of other applications.

Expedited Development and Review Programs for Drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs and biologics to get them to patients more quickly than standard FDA review timelines typically permit. We intend to apply for these programs for compounds, as applicable.

A new drug is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation applies to the compound and the specific indication for which it is being studied. The sponsor of a new drug product may request the FDA to designate the drug as a Fast Track product at any time during the clinical development of the product, but ideally no later than the pre-NDA meeting because many of the features of Fast Track designation will not apply after that time. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Rolling review means that the FDA may review portions of the marketing application before the sponsor submits the complete application.

In addition, a new drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, alone or in combination with one or more other drugs, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a drug product be designated as a Breakthrough Therapy at any time during the clinical development of the product and ideally before initiation of the pivotal clinical trial intended to serve as the primary basis for demonstration of efficacy to obtain the full benefits of the designation. Breakthrough Therapy designation provides all the features of Fast Track designation, in addition to intensive guidance on an efficient product development program beginning as early as phase 1 and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review and Accelerated Approval. A product is eligible for Priority Review, once an NDA is submitted, if the product that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Significant improvement may be illustrated by the following examples: evidence of increased effectiveness in treatment, prevention, or diagnosis of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. Under Priority Review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review.

The FDA may grant Accelerated Approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant Accelerated Approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM") and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of Accelerated Approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support Accelerated Approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The Accelerated Approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, Accelerated Approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit. Thus, the benefit of Accelerated Approval derives from the potential to receive approval based on surrogate endpoints sooner than possible for trials with clinical or survival endpoints, rather than deriving from any explicit shortening of the FDA approval timeline, as is the case with priority review.

The Accelerated Approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a compound approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to initiate expedited proceedings to withdraw approval of the product. All promotional materials for compounds approved under accelerated regulations are subject to prior review by the FDA. In addition, the FDA generally requires, as a condition for Accelerated Approval, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

Pediatric Study Plan and Pediatric Exclusivity

Under the Pediatric Research Equity Act, as amended (the "PREA"), certain NDAs and certain NDA supplements must contain data that can be used to assess the safety and efficacy of the compound for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. For a cancer drug directed at a molecular target, the pediatric testing requirement extends to pediatric cancers involving the molecular target even if different than the claimed adult cancer in the NDA. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The PREA requires that a sponsor who is planning to submit a marketing application for a compound that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (the "PSP"), within 60 days of an end-of-phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the phase 3 or phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs. Unless otherwise required by regulation, the PREA does not apply to a drug for an indication for which orphan drug designation has been granted, except that the PREA will apply to an original NDA for a new active ingredient that is orphan-designated if the drug is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

A drug can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

U.S. Post-Approval Requirements for Drugs

Drugs approved by FDA are subject to continuing regulation by the FDA, including, among other things, requirements relating to manufacturing establishment registration and product listing, recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, field alerts regarding issues with distributed product, promotion and advertising compliance, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe approved products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, as well as other advertising and promotion requirements, including not only by company employees but also by agents of the company or those speaking on the company's behalf, and a company that is found to have improperly promoted may be subject to significant liability, including investigation by federal and state authorities. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, untitled letters, corrective advertising, and potential civil and criminal penalties, including liabilities under the federal False Claims Act (the "FCA") where products obtain reimbursement under federal health care programs. Promotional materials for approved drugs must be submitted to the FDA in conjunction with their first use or first publication, and for products approved under accelerated approval prior to their first use. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may withdraw approval of a product if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or mandated modification of promotional materials and labeling and issuance of corrective information.

United States Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of future compounds, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Amendments”). The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process for a drug that has not been previously approved for commercial marketing. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Regulatory exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application (“ANDA”), or a 505(b)(2) NDA, submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of exclusivity for an NDA, 505(b)(2) NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and prevents FDA approval of an ANDA or 505(b)(2) NDA for such conditions of use, but does not prevent FDA acceptance for filing and review of an ANDA or 505(b)(2) NDA. The three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active agent for other conditions of use outside those protected by the exclusivity. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to evaluate maximum tolerated dose and effectiveness.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities of products following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services (“CMS”), other divisions of the U.S. Department of Health and Human Services (“HHS”), the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Healthcare Laws

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers, and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include federal and state anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including those described below.

- The federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from federal health care programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.

- The federal civil and criminal false claims laws, including the FCA, which can be enforced through civil “whistleblower” actions, and civil monetary penalty laws, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.

- The federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary, if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies.

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (including, public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

- The federal Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), imposed annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners.

- Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

- Analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current regulatory and healthcare environment, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Insurance Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing healthcare services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a compound is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government healthcare programs in the United States such as Medicare and Medicaid, private health insurers, managed care organizations and other third-party payors, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, principal decisions about Medicare reimbursement for new products are typically made by CMS and regional contractors responsible for administering the Medicare program. CMS and these contractors decide whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree.

Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is (1) a covered benefit under its health plan; (2) safe, effective and medically necessary; (3) appropriate for the specific patient; (4) cost-effective; and (5) neither experimental nor investigational. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. However, one third-party payor's determination to provide coverage for a compound does not assure that other payors will also provide coverage for the compound. No uniform policy of coverage and reimbursement for products exists among third-party payors, and coverage and reimbursement levels for products can differ significantly from payor to payor.

Third-party payors are increasingly challenging the prices charged, examining the medical necessity, reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmaco-economic studies in order to demonstrate the cost effectiveness of the product, which will require additional expenditure above and beyond the costs required to obtain FDA or other comparable regulatory approvals. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Moreover, the containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls or price increase penalties, restrictions on reimbursement and requirements for substitution of generic products.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical products, will apply to companion diagnostics.

Current and Future Healthcare Reform Legislation

In the United States and certain foreign jurisdictions, there have been, and likely will continue to be, a number of proposed and adopted legislative and regulatory changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under government health care programs. The ACA includes provisions of importance to our potential compounds that:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drug products, apportioned among these entities according to their market share in certain government healthcare programs;

- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- expanded the types of entities eligible for the 340B drug discount program;

- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and

- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, various portions of the ACA have faced legal and constitutional challenges, including in the United States Supreme Court; the Trump administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended in the future, and we cannot predict what effect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, included reductions of Medicare payments to providers of 2%, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, including bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in numerous Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, former President Trump used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders, and policy initiatives. It is unclear whether the Biden administration will work to reverse those measures or pursue similar or other policy initiatives, for example related to an independent review board or other mechanisms that would impact drug pricing and reimbursement.

On November 20, 2020, CMS and the HHS Office of the Inspector General issued two final rules implementing changes to the Physician Self-Referral Law, or Stark Law, and the Anti-Kickback Statute. These new rules provide new value-based enterprise exceptions and safe harbors to the Stark Law and the Anti-Kickback Statute, as well as offer additional clarification in the form of updated definitions.

Compliance with Other Federal and State Laws or Requirements; Changing Legal Requirements

If any products that we may develop are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, labeling, packaging, distribution, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to which we may be subject. The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive recordkeeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products, and state licensure.

The failure to comply with any of these laws or regulatory requirements may subject firms to legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling or packaging; (3) the recall or discontinuation of our products; or (4) additional recordkeeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Government Regulation of Drugs Outside of the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, manufacturing, commercial sales and distribution of our products. These regulatory requirements may be similarly complex and even more stringent in certain regards than those described above. If we fail to comply with applicable regulatory requirements in the jurisdiction where we conduct clinical trials or seek regulatory approvals, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

For instance, in the European Economic Area (the "EEA") (comprising the 27 European Union member states plus Iceland, Liechtenstein and Norway), medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

- Centralized procedure—The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the EEA. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products (gene therapy, somatic cell therapy and tissue engineered products) and products with a new active substance indicated for the treatment of certain diseases, which includes products for the treatment of cancer. For medicines that do not fall within one of the mandatory categories, an applicant still has the option of submitting an application for a centralized marketing authorization to the European Medicines Agency (the "EMA"), as long as the medicine concerned contains a new active substance not authorized in the EEA prior to May 20, 2004, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EEA. If pursuing marketing authorization for one of our compounds for a therapeutic indication under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use (the "CHMP"), is responsible for conducting an initial assessment of whether a product meets the required quality, safety and efficacy requirements, and whether a product has a positive benefit/risk ratio. Under the centralized procedure the maximum timeframe for the evaluation of a marketing authorization application (the "MAA"), by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a MAA under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

- National authorization procedures—There are also two other possible routes to authorize products for therapeutic indications in several countries, which are available for products that fall outside the scope of the centralized procedure:

- Decentralized procedure—Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EEA member state for a medicinal product that has not yet been authorized in any EEA member state and that does not fall within the mandatory scope of the centralized procedure.

- Mutual recognition procedure—In the mutual recognition procedure, a medicine is first authorized in one EEA member state, in accordance with the national procedures of that country. Following this, additional marketing authorizations can be sought from other EEA member states in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

In both cases, as with the centralized procedure, the competent authorities of the EEA member states assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy before granting the marketing authorization.

In the EEA, new products for therapeutic indications that are authorized for marketing (so called “references products”) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from referencing the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EEA during a period of eight years from the date on which the reference product was first authorized in the EEA. The additional two-year period of market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EEA until ten years have elapsed from the initial authorization of the reference product in the European Union. The overall ten-year period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new active substance so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on a MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

The criteria for designating an “orphan medicinal product” in the EEA are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, in the EEA a medicinal product may be designated as orphan if it meets the following criteria (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; and (2) either (a) such condition affects no more than five in 10,000 persons in the EEA when the application is made, or (b) it is unlikely that the product, without the benefits derived from orphan status, would generate sufficient return in the EEA to justify the investment needed for its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition, or if such a method exists, the product will be of significant benefit to those affected by the condition. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year orphan market exclusivity period, no marketing authorization application shall be accepted, and no marketing authorization shall be granted for a similar medicinal product for the same indication, although similar, is safer, more effective or otherwise clinically superior than the authorized product; (ii) the marketing authorization holder of the authorized product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder of the authorized product cannot supply enough orphan medicinal product. An orphan product can also obtain an additional two years of market exclusivity in the EEA for pediatric studies. The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Similar to the United States, the various phases of non-clinical and clinical research in the European Union are subject to significant regulatory controls.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual European Union member states govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the national competent authority (the "NCA"), of the European Union member states in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee (the "EC"), has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, and the provisions of the individual European Union member states' legislation implementing the Clinical Trials Directive. Under the current regime (the European Union Clinical Trials Directive 2001/20/EC and corresponding national laws) all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the member state where they occurred.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (the "Clinical Trials Regulation") was adopted, which is expected to apply following confirmation of full functionality of the Clinical Trials Information System, the centralized European Union portal and database for clinical trials foreseen by the regulation, through an independent audit. The regulation becomes applicable six months after the European Commission publishes notice of this confirmation, which it has not yet done. The Clinical Trials Regulation will be directly applicable in all the European Union member states, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by the Clinical Trials Directive and the member states' national implementing legislation until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial. The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the "European Union portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all European Union member states in which an application for authorization of a clinical trial has been submitted (member states concerned). Part II is assessed separately by each member state concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned European Union member state. However, overall related timelines will be defined by the Clinical Trials Regulation.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed upon. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular compound to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade, in other words, arbitrage between low- priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Government Regulation of Data Collection Outside of the United States

In the event we conduct clinical trials in the European Union, we will be subject to additional privacy restrictions. The collection and use of personal health data in the EEA is governed by the General Data Protection Regulation (the "GDPR"), which became effective on May 25, 2018. The GDPR applies to the processing of personal data by any company established in the EEA and to companies established outside the EEA to the extent they process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, enhanced requirements for securing personal data, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA member states, which may deviate slightly from the GDPR, may result in fines of up to 4% of a company's global revenue for the preceding financial year, or €20 million, whichever is greater. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR will require significant time, resources and expense, and we may be required to put in place additional controls and processes ensuring compliance with the new data protection rules. There has been limited enforcement of the GDPR to date, particularly in biopharmaceutical development, so we face uncertainty as to the exact interpretation of the new requirements on any future trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. Further, the United Kingdom's decision to leave the European Union, means that it has in force its own legislation, which is aligned with the GDPR, known as the Data Protection Act 2018. The requirements are similar except that the United Kingdom is now regarded as a "third country" for the purposes of transfers of personal data from the EEA. Transfers continue to flow freely from the UK to the EEA following an adequacy decision from the European Commission adopted on June 28, 2021 and valid for four years.

Data protection authority activity differs across the European Union, with certain authorities applying their own agenda which shows there is uncertainty in the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the European Union, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance are onerous and may adversely affect our business, financial condition, results of operations and prospects.

Should we utilize third-party distributors, compliance with such foreign governmental regulations would generally be the responsibility of such distributors, who may be independent contractors over whom we have limited control.

Recent Developments of the Company

Effective March 13, 2024, our board of directors has appointed Francis Knuettel II as Chief Executive Officer of the Company. Mr. Knuettel will serve as the Company's Chief Executive Officer until a successor is duly elected and qualified, unless sooner removed. In addition to his role as Chief Executive Officer of the Company, Mr. Knuettel will continue to serve in his capacity as Chief Financial Officer, Treasurer and Secretary of the Company.

Corporate Information

Chromocell Holdings, our predecessor, was founded in 2002 to commercialize "Chromovert Technology," a proprietary discovery technology with a potential broad range of applications in the biomedical field, including the potential capability to create complex targets (cell-lines) needed for effective high-throughput screening that is commonly used both in therapeutics and flavors discovery. Initially, Chromocell Holdings focused on applications in the food and flavors space.

In 2012, Chromocell Holdings started applying the technology in the therapeutics area. Chromocell Holdings focused its efforts on projects where it believed that the discovery of novel medications was largely held back by difficulties creating complex targets (cell lines) needed for effective high-throughput screening. The NaV1.7 ion-channel is a complex target with a well-established role in pain modulation and management believed it presented an opportunity to apply the technology in an area of unmet medical need. Upon creating the necessary NaV1.7 assays and conducting a large high-throughput campaign, Chromocell Holdings' research team discovered CC8464. After pre-clinical studies and assessments, an IND was filed and CC8464 was evaluated in a Phase 1 study with more than 100 subjects. In 2015, Chromocell Holdings signed an agreement with Astellas Pharma Inc. ("Astellas") for the joint development and commercialization of CC8464. Astellas terminated such agreement in 2018 and returned all rights, including all intellectual property rights on CC8464, to Chromocell Holdings.

As both the flavors and the therapeutics businesses grew and increasingly required different expertise, capital and business concepts, Chromocell Holdings made the strategic decision to separate the two businesses.

Chromocell Therapeutics Corporation was incorporated in Delaware on March 19, 2021.

Our principal executive offices are located at 4400 Route 9 South, Suite 1000, Freehold, NJ 07728, and our telephone number is (732) 514-2636. Our website is www.chromocell.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Report, and you should not consider information on our website to be part of this Report.

We make available free of charge under the "Investors" section of our website all of our filings with the Securities and Exchange Commission (the "SEC"), including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and amendments to such documents, each of which is provided on our website as soon as reasonably practicable after we electronically file or furnish, as applicable, the information with the SEC.

Implications of Being an Emerging Growth and Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the JOBS Act. An emerging growth company may take advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- reduced obligations with respect to financial data;
- an exception from compliance with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act");

- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions for up to five years or such earlier time that we no longer qualify as an emerging growth company. We would cease to be an emerging growth company upon the earliest of:

- the last day of the fiscal year on which we have $1.235 billion or more in annual revenue,
- the date on which we become a “large accelerated filer” (i.e., as of our fiscal year end, the total market value of our common equity securities held by non-affiliates is $700 million or more as of June 30),
- the date on which we issue more than $1.0 billion of non-convertible debt over a three-year period, or
- the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO.

We may choose to take advantage of some but not all of these reduced reporting burdens.

In addition, under the JOBS Act, emerging growth companies can take advantage of an extended transition period and delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for private companies. If we were to subsequently elect instead to comply with public company effective dates, such election would be irrevocable pursuant to the JOBS Act.

Also, we are a “smaller reporting company” (and may continue to qualify as such even after we no longer qualify as an emerging growth company). For as long as we qualify as a “smaller reporting company,” we may provide reduced disclosure in the public filings that we make with the SEC than larger public companies, such as the inclusion of only two years of audited financial statements and only two years of management’s discussion and analysis of financial condition and results of operations disclosure.

As a result of qualifying as an emerging growth company and a smaller reporting company, to the extent we take advantage of the allowable reduced reporting burdens, the information that we provide to our stockholders may be different than what you might receive from other public reporting companies in which you hold equity interests.

Item 1A. Risk Factors

Our business, financial condition and operating results are subject to a number of risk factors, both those that are known to us and identified below and others that may arise from time to time. These risk factors could cause our actual results to differ materially from those suggested by forward-looking statements in this Report and elsewhere, and may adversely affect our business, financial condition or operating results. If any of these risk factors should occur, moreover, the trading price of our securities could decline, and investors in our securities could lose all or part of their investment in our securities. These risk factors should be carefully considered in evaluating our prospects.

Summary of Risk Factors

Our business is subject to a number of risks that you should be aware of before making an investment decision to purchase our securities. You should carefully consider all of the information set forth in this Report and, in particular, should evaluate the specific factors set forth in the section titled “Risk Factors” in deciding whether to invest in our securities. Among these important risks are the following:

- The report of the independent registered public accounting firm on our 2023 and 2022 financial statements contains a going concern qualification;
- We are a clinical stage biopharmaceutical company with a limited operating history;

- We have incurred net losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability;
- We have identified material weaknesses in our internal control over financial reporting;
- We will need to raise additional funding to receive approval for CC8464, CT2000 or any other future compound. Such funding may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit, sell or terminate certain of our product development efforts or other operations;
- We may be subject to litigation for a variety of claims, which could adversely affect our results of operations, harm our reputation or otherwise negatively impact our business;
- We are early in our efforts to develop CC8464, which is the only compound that we have advanced into clinical development. If we are unable to advance CC8464 through clinical trials, obtain regulatory approval and ultimately commercialize CC8464, or if we experience significant delays in doing so, our business will be materially harmed;
- We are early in our efforts to develop CT2000, and have not moved into pre-clinical or clinical trials. If we are unable to advance CT2000 through pre-clinical and clinical trials, obtain regulatory approval and ultimately commercialize CT2000, or if we experience significant delays in doing so, our business will be materially harmed;
- CC8464 is in early-stage development, and there is no guarantee that the results from prior clinical and preclinical studies will be indicative of our ability to complete or the results to be obtained in the current or future studies and clinical trials. CC8464 is our only compound in clinical development and advancing a different compound would require substantial time and resources as well as being subject to the same risks and uncertainties as described here for CC8464;
- We may encounter substantial delays in our clinical trials, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities;
- Our drug development costs will increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all;
- Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize CC8464 and CT2000 and the approval may be for a narrower indication than we seek;
- CC8464 and CT2000 may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval;
- CC8464 and CT2000 are based on specific modes of administration (dose escalation regime and eye drops, respectively), which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval;
- Even if we obtain regulatory approval for CC8464 and CT2000, our only compounds in clinical development will remain subject to regulatory oversight;
- Even if we obtain and maintain approval for CC8464 and CT2000 from the FDA, we may never obtain approval for them outside of the United States, which would limit our market opportunities and adversely affect our business;
- While we plan to apply for orphan drug designation for CC8464 in the future, it may not effectively protect us from competition, and we may be unable to obtain similar designations for our future compounds. For instance, if our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as our lead compounds before us, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time. To date, we have not submitted an application for orphan drug designation;

- FDA designations to expedite drug development and review, including “orphan drug” designation, Breakthrough Therapy designation, and/or Fast Track designation, even if granted for any of our compounds, may not lead to a faster development, regulatory review or approval process and do not increase the likelihood that any of our compounds will receive marketing approval in the United States;

- We may expend our limited resources to pursue a compound or indication and fail to capitalize on our compounds or indications that may be more profitable or for which there is a greater likelihood of success;

- If we are not successful in discovering, developing and commercializing additional compounds, our ability to expand our business and achieve our strategic objectives would be impaired;

- We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize CC8464 and CT2000;

- On December 23, 2023, we entered into the Benuvia License Agreement. We are dependent on the Benuvia License Agreement, and the termination of the Benuvia License Agreement could have an adverse effect on our business;

- If Benuvia does not properly maintain or enforce the intellectual property underlying the Benuvia License Agreement, our competitive position and business prospects could be harmed. Benuvia may also seek to terminate our license;

- Rizatriptan is an off-patent branded generic that can be manufactured and sold by other pharmaceutical manufacturers, which may increase the competition we face and reduce our ability to diversify our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions under the Benuvia License Agreement;

- Delays in obtaining regulatory approvals of the process and facilities needed to manufacture CC8464, CT2000 or any other compounds or disruptions in our manufacturing process may delay or disrupt our product development and commercialization efforts;

- Any contamination in our manufacturing process, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules;

- If we are unable to expand our market development capabilities or enter into agreements with third parties to market and sell our compounds, we may be unable to generate any revenue;

- If the market opportunities for CC8464, CT2000 or our future compounds are smaller than we believe they are, our revenues may be adversely impacted, and our business may suffer;

- Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for CC8464 and CT2000, if approved, or any of our other future compounds that may be approved in the future, which would adversely affect our revenue and results of operations;

- The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our products, if approved, could limit our ability to market those products and decrease our ability to generate product revenue;

- We may not be successful in our efforts to identify or discover additional compounds and may fail to capitalize on programs or compounds that may be a greater commercial opportunity or for which there is a greater likelihood of success;
- If we are unable to manage expected growth in the scale and complexity of our operations, our performance may suffer;
- Our future success depends on our ability to retain key employees and scientific advisors and to attract, retain and motivate qualified personnel;
- Our employees, principal investigators and advisors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements;
- We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties;
- If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business;
- Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations;
- Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and financial condition and results of operations;
- A pandemic, epidemic, or outbreak of an infectious disease, such as SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) ("COVID-19"), may materially and adversely affect our business and our financial results and could cause a disruption to the development of our compounds;
- Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs;
- Cyber-security incidents, including data security breaches or computer viruses, could harm our business by disrupting our delivery of services, damaging our reputation or exposing us to liability;
- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop;
- If we are unable to obtain and maintain adequate U.S. and foreign patent protection for our compounds, including CC8464 and CT2000, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technologies similar or identical to ours, and our ability to successfully commercialize CC8464, CT2000 and any of our other current or future compounds may be adversely affected;
- We may not be able to protect our intellectual property or enforce our intellectual property rights adequately throughout the world;

- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business;
- Third parties may initiate legal or administrative proceedings attacking the validity of our patents protecting CC8464, CT2000 and future compounds the outcome of which would be uncertain and could have a material adverse effect on the success of our business;
- Instituting and defending against patent and other types of intellectual property litigation and administrative proceedings could cause us to spend substantial resources, distract our personnel from their normal responsibilities, and have uncertain outcomes;
- Changes in United States patent law and its administrative and judicial interpretation could diminish the value of patents in general, thereby impairing our ability to protect our compounds;
- Intellectual property rights and regulatory exclusivity rights do not necessarily address all potential threats;
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed;
- The market price and trading volume of the Company's common stock, par value $0.0001 per share ("Common Stock") may experience rapid and substantial volatility, which could cause purchasers of our Common Stock to incur substantial losses;
- Our Common Stock is currently listed on the NYSE American LLC (the "NYSE American"). NYSE American may delist our Common Stock from trading, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions;
- Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management;
- Our amended and restated certificate of incorporation (which, as so amended and restated, we refer to as our "certificate of incorporation") and our bylaws, as amended (which we refer to as our "bylaws") provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees;
- The Series C Convertible Redeemable Preferred Stock of the Company, par value of $0.0001 per share (the "Series C Preferred Stock") has a liquidation preference over our Common Stock;
- The price of our securities may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our securities;
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies, CC8464 or CT2000;
- We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make our Common Stock less attractive to investors;

- We will incur increased costs as a result of operating as a smaller reporting public company, and our management will be required to devote substantial time to new compliance initiatives;

- Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain;

- Our business could be adversely impacted if there are deficiencies in our disclosure controls and procedures or our internal control over financial reporting;

- There is no assurance that we will enter into our proposed Equity Line of Credit (the "ELOC") or that the terms thereof will be consistent with or as favorable as those described in this Report;

- Issuances of our Common Stock to the holder of the promissory note, as amended from time to time, in the aggregate principal amount of $450,000 that the Company entered into on February 4, 2022, as amended (the "Investor Note") (the "Holder of the Investment Note");

- Our existing stockholders may experience significant dilution from the sale of our shares of Common Stock pursuant to our proposed ELOC;

- We may not have access to the full amount available under our proposed ELOC;

- The Holder of the Investor Note will pay less than the then-prevailing market price for shares of our Common Stock, which could cause the price of our Common Stock to decline; and

- The other factors set forth under "Risk Factors."

These and other risks are more fully described in the section entitled "Risk Factors" in this Report. If any of these risks actually occurs, our business, financial condition, results of operations, cash flows, and prospects could be materially and adversely affected. As a result, you could lose all or part of your investment in our securities.

Risks Related to Our Business

The report of the independent registered public accounting firm on our 2023 and 2022 financial statements contains a going concern qualification.

The report of the independent registered public accounting firm covering our financial statements for the years ended December 31, 2023 and 2022 stated that certain factors, including that we have suffered recurring losses from operations and have an accumulated deficit at December 31, 2023, raised substantial doubt as to our ability to continue as a going concern. Because we are not yet producing sufficient revenue to sustain our operating costs, we are dependent upon raising capital to continue our business. If we are unable to raise capital, we may be unable to continue as a going concern.

We are a clinical stage biopharmaceutical company with a limited operating history.

The operations of our company, contributed to us by Chromocell Holdings, to date have been limited to financing and staffing our Company, developing and licensing compounds, conducting preclinical and clinical studies of CC8464 for EM and iSFN, CT2000 for eye pain and other pain indications. We have not yet demonstrated the ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially early-stage clinical pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to, among other things:

- successfully implement or execute our current business plan, and we cannot assure you that our business plan will lead to an approval or successful commercialization;

- successfully manufacture our compounds and establish commercial supply;

- successfully complete the clinical trials necessary to obtain regulatory approval for the marketing of CC8464;
- secure market exclusivity and/or adequate intellectual property rights for our compounds in each jurisdiction in which we do or plan to commercialize our compounds or where our competitors are organized or may engage in competitive activity;
- attract and retain an experienced management and advisory team;
- secure acceptance of our compounds in the medical community and with third-party payors and consumers;
- raise sufficient funds in the capital markets or otherwise to effectuate our business plan; and
- utilize the funds that we do have and/or raise in this offering or in the future to efficiently execute our business strategy.

If we cannot successfully execute any one of the foregoing, our business may fail and your investment will be adversely affected.

We have incurred net losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

There are numerous risks and uncertainties associated with pharmaceutical product and biological development, and we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

We have had net losses since inception, and we had an accumulated deficit of approximately $13.5 million and $6.1 million as of December 31, 2023 and December 31, 2022, respectively, which includes a net loss of approximately $7.4 million for year ended December 31, 2023, and approximately $2.5 million the year ended December 31, 2022, respectively. Overall, these conditions have raised substantial doubt regarding our ability to continue as a going concern beyond one year of the filing of our financial statements. Our ability to continue as a going concern is dependent upon the ability to complete clinical studies and implement our business plan, raise capital, generate sufficient revenues and to control operating expenses.

We have primarily financed our operations through a combination of a series of cash advances, equity raises, bridge and promissory note issuances, licensing arrangements, government grants and the IPO (from which we raised net proceeds of approximately $5.7 million, after deducting underwriting discounts, commissions and other offering expenses). Our ability to achieve significant profitability depends on our ability to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, CC8464, CT2000 and/or additional compounds. We expect that it will take several years, if ever, before we have a commercialized compound. The net losses we incur may fluctuate significantly from quarter to quarter.

If we are required by the FDA, the EMA, or other international regulatory authorities to which we may be subject, to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of CC8464, CT2000 and/or other future compounds, our expenses could increase and revenue could be further delayed. We anticipate that our expenses will increase substantially if, and as, we:

- continue our research and the clinical development of CC8464 and CT2000;
- launch in vivo and toxicology studies of CT2000 for the treatment of eye pain;
- initiate additional clinical trials and preclinical studies for any additional compounds that we may pursue in the future;

- prepare an NDA for filing with the FDA, a marketing authorization application, and approvals in certain other countries;
- oversee the manufacturing of material for clinical trials or potential commercial sales;
- develop a portfolio of compounds;
- establish a business development operation to in- our out-license certain assets;
- establish a sales, marketing and distribution infrastructure to commercialize any compound for which we may obtain marketing approval;
- develop, maintain, expand, protect and enforce our intellectual property rights portfolio; and/or
- acquire or in-license other compounds and technologies.

To become and remain profitable, we must develop and eventually commercialize one or more compounds with significant market potential. This will require us to be successful in a range of challenging activities, including completing the clinical trials, developing and validating commercial scale manufacturing processes, obtaining marketing approval for our compounds, manufacturing, and marketing. Licensing and selling any future compounds for which we may obtain marketing approval and satisfying any post-marketing requirements. If we were required to discontinue development of CC8464 or CT2000, if CC8464 or CT2000 does not receive regulatory approval, if we do not obtain our targeted indication(s) for CC8464 or CT2000, or if CC8464 or CT2000 fails to achieve sufficient market acceptance for any indication, we could be delayed by many years in our ability to achieve profitability. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

Our business could be adversely impacted if there are deficiencies in our disclosure controls and procedures or our internal control over financial reporting.

The design and effectiveness of our disclosure controls and procedures and our internal control over financial reporting may not prevent all errors, misstatements or misrepresentations. There can be no guarantee that our disclosure controls and procedures and internal control over financial reporting will be effective in accomplishing all control objectives all of the time. Deficiencies, including any material weaknesses, in our disclosure controls and procedures or internal control over financial reporting could result in misstatements of our results of operations or our financial statements or could otherwise materially and adversely affect our business, reputation, results of operations, financial condition or liquidity.

We have identified material weaknesses in our internal control over financial reporting.

Prior to our IPO, we were a private company and had limited accounting and financial reporting personnel and other resources with which to address our internal controls and related procedures. In connection with the audit and review, as applicable, of our financial statements for the years ended December 31, 2023 and 2022, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses in our case arose from inadequate segregation of duties, ineffective information technology controls and lack of certain financial reporting and transaction processing controls. If we are unable to remedy our material weaknesses, or if we generally fail to establish and maintain effective internal controls appropriate for a public company, we may be unable to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price.

We will need to raise additional funding to receive approval for CC8464, CT2000 or any other future compound. Such funding may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit, sell or terminate certain of our product development efforts or other operations.

To complete the process of obtaining regulatory approval for CC8464 and CT2000 and to build the sales, marketing, licensing and distribution infrastructure that we believe will be necessary to commercialize CC8464 and CT2000, if approved, we will require substantial additional funding. In addition, if we obtain marketing approval for CC8464 and CT2000, we expect to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution.

Our future capital requirements will depend on many factors, including:

- the progress, timing, results and costs of our phase 2a clinical trial for CC8464;
- the progress, timing, results and costs of our formulation efforts and pre-clinical trials for CT2000;
- the progress, timing and costs of manufacturing clinical trial for our planned pivotal clinical trials;
- the potential development and the filing on an IND application for other future compounds;
- the initiation, scope, progress, timing, costs and results of drug discovery, laboratory testing, manufacturing, preclinical studies and clinical trials for any other future compounds that we may pursue in the future, if any;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs associated with the manufacturing process development and evaluation of third-party manufacturers;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, in the event we receive marketing approval for CC8464, CT2000 or any other future compounds we may develop;
- the extent to which the costs of future compounds, if approved, will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors;
- the costs of commercialization activities for CC8464, CT2000 and other future compounds if we receive marketing approval for CC8464, CT2000 or any other future compounds we may develop, including the costs and timing of establishing product sales, medical affairs, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, if any, revenue received from commercial sale of CC8464, CT2000 or any of our other future compounds;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
- the amount and timing of any payments we may be required or decide to make, or that we may receive, in connection with the licensing, filing, prosecution, maintenance, and enforcement of any patents or other intellectual property rights and defense against third party intellectual property infringement claims, including milestone and royalty payments and patent prosecution fees that we are obligated to pay pursuant to our license agreements, if any;
- the development of alternative treatments for EM or iSFN or other pain indications;
- our ability to establish and maintain collaborations and licenses on favorable terms, if at all; and
- the extent to which we acquire or in-license other compounds and technologies.

Identifying potential compounds and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. Our lead compounds, if approved, may not achieve commercial success. Our future compound's revenues, if any, will be derived from or based on sales of compounds that may not be commercially available for many years, if at all. Accordingly, it is unlikely that we will generate product or licensing revenue during the next twelve months and will need to continue to rely on additional financing to achieve our business objectives. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize future compounds. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and a portion of our operating cash flows, if any, being dedicated to the payment of principal and interest on such indebtedness, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Furthermore, existing securityholders may not agree with our financing plans or the terms of such financings. Adequate additional financing may not be available to us on acceptable terms, or at all. The terms of additional financing may be impacted by, among other things, general market conditions, and the market's perception of future compounds. If adequate funds are not available, we may be required to curtail our operations or other business activities or obtain funds through arrangements with strategic partners or others that may require us to relinquish rights to certain technologies or potential markets.

We may be subject to litigation for a variety of claims, which could adversely affect our results of operations, harm our reputation or otherwise negatively impact our business.

We may be subject to litigation for a variety of claims arising from our normal business activities. These may include claims, suits, and proceedings involving labor and employment, wage and hour, commercial and other matters. The outcome of any litigation, regardless of its merits, is inherently uncertain. Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. Any adverse determination related to litigation could adversely affect our results of operations, harm our reputation or otherwise negatively impact our business. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter could materially affect our future operating results, our cash flows or both.

Risks Related to Development, Clinical Testing, and Regulatory Approval

We are early in our efforts to develop CC8464, which is the only compound that we have advanced into clinical development. If we are unable to advance CC8464 through clinical trials, obtain regulatory approval and ultimately commercialize CC8464, or if we experience significant delays in doing so, our business will be materially harmed.

We are early in our development of CC8464. The development and commercialization of CC8464 (or any other compound that we may advance towards clinical development in the future) is subject to many uncertainties, including the following:

- successful enrollment and completion of the two studies we are planning to conduct in the next phase of our clinical trials (Phase 2);
- positive results from our current and planned future clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities;
- successful development of our internal manufacturing processes on an ongoing basis and maintenance of our potential future arrangements with third-party manufacturers for clinical supply;
- commercial launch of CC8464, if and when approved, whether alone or in collaboration with others; and

- acceptance of CC8464, if and when approved, by patients, the medical community and third-party payors.

If we fail in one or more of these factors, we could experience significant delays or an inability to successfully commercialize CC8464, which would materially harm our business. If we do not receive regulatory approvals for CC8464, our business, financial condition, results of operations and prospects could be materially and adversely affected. Advancing a different compound than CC8464 towards clinical development would take substantial time and resources and be subject to the same risks as described here for CC8464.

We are early in our efforts to develop CT2000, and have not moved into pre-clinical or clinical trials. If we are unable to advance CT2000 through pre-clinical and clinical trials, obtain regulatory approval and ultimately commercialize CT2000, or if we experience significant delays in doing so, our business will be materially harmed.

We are early in our development of CT2000. The development and commercialization of CT2000 (or any other compound that we may advance towards clinical development in the future) is subject to many uncertainties, including the following:

- successful completion of the formula for eye drops;
- positive results from our planned future pre-clinical and clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities;
- successful development of our internal manufacturing processes on an ongoing basis and maintenance of our potential future arrangements with third-party manufacturers for clinical supply;
- commercial launch of CT2000, if and when approved, whether alone or in collaboration with others; and

- acceptance of CT2000, if and when approved, by patients, the medical community and third-party payors.

If we fail in one or more of these factors, we could experience significant delays or an inability to successfully commercialize CT2000, which would materially harm our business. If we do not receive regulatory approvals for CT2000, our business, financial condition, results of operations and prospects could be materially and adversely affected. Advancing a different compound than CT2000 towards clinical development would take substantial time and resources and be subject to the same risks as described here for CT2000.

CC8464 is in early-stage development, and there is no guarantee that the results from prior clinical and preclinical studies will be indicative of our ability to complete or the results to be obtained in the current or future studies and clinical trials. CC8464 is our only compound in clinical development and advancing a different compound would require substantial time and resources as well as being subject to the same risks and uncertainties as described here for CC8464.

There is no guarantee that results of our potential future clinical trials will be positive or that we will be able to complete this or any potential future clinical trials on the anticipated timelines or at all. Furthermore, research and discoveries by us or others may identify serious adverse events, undesirable side effects or other unexpected properties of our current and future compounds, including CC8464, that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

The regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a future compound for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or post-approval safety monitoring program. These regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of CC8464. Any of the foregoing scenarios could materially harm the commercial prospects for CC8464 and materially and adversely affect our business, financial condition, results of operations and prospects.

We may encounter substantial delays in our pre-clinical and clinical trials, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our drug candidates, CC8464 and CT2000 included, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug candidate for its intended indications. Clinical trials are expensive, time consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching a consensus with regulatory authorities on trial design;
- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or concerns with a class of drug candidates, or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;

- occurrence of serious adverse events associated with the drug candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

In addition, if we have to make manufacturing or formulation changes to CC8464, we would need to conduct additional studies to bridge our modified compound to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize CC8464 or allow our competitors to bring products to market before we do, which could limit our potential revenue or impair our ability to successfully commercialize CC8464 and may harm our business, financial condition, results of operations and prospects. Any delays, setbacks or failures in our clinical trials could materially and adversely affect our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our drug candidates, we may:

- be delayed in obtaining marketing approval, if at all, or be required to conduct additional confirmatory safety and/or efficacy studies causing additional expenses;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

As CC8464 is our only compound in clinical development, any setback may have a significant negative effect on our business.

Our drug development costs will increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

We, the FDA or an Institutional Review Board may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our IND applications or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our drug candidates could be negatively impacted, and our ability to generate revenues from our drug candidates may be delayed. As CC8464 is our only compound in clinical development, any setback may have a significant negative effect on our business.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize CC8464 and CT2000 and the approval may be for a narrower indication than we seek.

We cannot commercialize a compound until the appropriate regulatory authorities have reviewed and approved the compound. Even if CC8464 and CT2000 meet their respective safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a compound for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a post-approval safety monitoring program. These regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of CC8464 and CT2000. Any of the foregoing scenarios could materially harm the commercial prospects for CC8464 and CT2000 and materially and adversely affect our business, financial condition, results of operations and prospects as CC8464 is our only compound in clinical development and CT2000 has not yet entered pre-clinical trials.

CC8464 and CT2000 may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

Our Phase 1 clinical trials have shown that CC8464 can lead to rashes. In addition to this side effect and possibly others caused by CC8464, the administration process or related procedures also can cause adverse side effects. If any such adverse events occur, our clinical trials could be suspended or terminated. If in the future we are unable to demonstrate that such adverse events were caused by the administration process or related procedures, the FDA, the European Commission, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, CC8464 for any or all targeted indications. Even if we can demonstrate that any serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of CC8464, the commercial prospects of such compound may be harmed and our ability to generate revenues from this compound may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly. As CC8464 is our only compound in clinical development, any setback may have a significant negative effect on our business.

Additionally, if CC8464 receives marketing approval, the FDA could require us to adopt a post-approval safety monitoring program to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by CC8464, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such compound;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a compound is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of CC8464 and could significantly harm our business, financial condition, results of operations and prospects.

Additionally, other regulatory regimes in other geographies, such as the European Union, India and Japan, where we are initially targeting our products, may impose similar conditions or post-monitoring requirements as a result of such findings.

We have yet to begin evaluating CT2000 to determine if it has any side effects, but could face similar or other issues, including but not limited to the disclosures set forth above for CC8464 with respect to FDA approval, ongoing monitoring programs and label requirements.

CC8464 and CT2000 are based on specific modes of administration (dose escalation regime and eye drops, respectively), which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

The clinical trial requirements of the FDA, EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a compound vary substantially according to the type, complexity, novelty and intended use and market of such compounds. The regulatory approval process for novel compounds such as ours can be more expensive and take longer than for other, better known or more extensively studied compounds.

Regulatory requirements governing pain medication products have been changing as side effects and the addictive nature of opioids became more apparent. The regulatory framework for pain medications has been tightened and these changes may affect our programs and its commercial potential despite our expectations that CC8464 will not show addictive features. While we are subject to the FDA and EMA regulatory regimes, these are not the only regulatory regimes to which we may be subject in the event we are able to execute on our objectives.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of CC8464 or future compounds or lead to significant post-approval limitations or restrictions. As we advance CC8464, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of CC8464. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects would be materially and adversely affected.

Even if we obtain regulatory approval for CC8464 and CT2000, our compounds will remain subject to regulatory oversight.

Even if we obtain any regulatory approval for CC8464 and CT2000, our lead compounds, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for CC8464 and CT2000 may also be subject to a post-approval safety monitoring program, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. For example, the holder of an approved NDA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of CC8464, CT2000 or any future compound, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of compounds; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize CC8464 and CT2000 and adversely affect our business, financial condition, results of operations and prospects.

The FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of CC8464 and CT2000. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would materially and adversely affect our business, financial condition, results of operations and prospects.

Even if we obtain and maintain approval for CC8464 and CT2000 from the FDA, we may never obtain approval for them outside of the United States, which would limit our market opportunities and adversely affect our business.

Approval of a compound in the United States by the FDA does not ensure approval of such compound by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of CC8464 and CT2000 or other future compounds outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a compound, comparable regulatory authorities of foreign countries also must approve the manufacturing and marketing of the compound in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a compound must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our compounds, if approved, is also subject to approval. We intend to submit a marketing authorization application to the EMA for approval of CC8464 and CT2000 in the European Union, but obtaining such approval from the European Commission following the opinion of the EMA is a lengthy and expensive process. Even if a compound is approved, the FDA or the European Commission, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the European Union also have requirements for approval of compounds with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our compounds in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for any of our compounds may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of CC8464, CT2000 or our future compounds will be harmed and our business, financial condition, results of operations and prospects will be adversely affected.

While we plan to apply for orphan drug designation for CC8464 in the future, it may not effectively protect us from competition, and we may be unable to obtain similar designations for our future compounds. For instance, if our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as our lead compounds before us, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time. To date, we have not submitted an application for orphan drug designation.

In connection with the application for one of our two lead compounds, CC8464, for the treatment of EM and iSFN, we also plan to seek orphan drug designation from the FDA. As of the date of this Report, we have not submitted an application for orphan drug designation for CC8464. Under the Orphan Drug Act of 1983, the FDA may designate a compound as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

Generally, if a compound with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before we do (regardless of our orphan drug designation), we will be precluded from receiving marketing approval for our product for the applicable exclusivity period. The applicable period is seven years in the United States.

Even though we may obtain orphan drug exclusivity for CC8464, that exclusivity may not effectively protect the compound from competition because different drugs can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, marketing authorization may be granted to a similar medicinal product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although like the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply enough quantities of orphan medicinal product.

If we are not able to secure an orphan drug designation, or if the exclusivity associated with such designation does not effectively protect us from competition, our business, financial condition, results of operations and prospects will be adversely affected.

FDA designations to expedite drug development and review, including "orphan drug" designation, Breakthrough Therapy designation, and/or Fast Track designation, even if granted for any of our compounds, may not lead to a faster development, regulatory review or approval process and do not increase the likelihood that any of our compounds will receive marketing approval in the United States.

As with any future application for "orphan drug" designation for CC8464 from the FDA, there is no assurance that any of our other compounds that we may develop in the future will receive a similar designation from the FDA or that we will receive Breakthrough Therapy or Fast Track designations for our compounds. Further, even if we do receive favorable designations from the FDA, the receipt of any of these designations may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA.

We may expend our limited resources to pursue a compound or indication and fail to capitalize on our compounds or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other of our compounds or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and our lead compounds for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular compound, we may relinquish valuable rights to that compound through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such compound.

If we are not successful in discovering, developing and commercializing additional compounds, our ability to expand our business and achieve our strategic objectives would be impaired.

Although a substantial amount of our effort initially focuses on developing CC8464 and CT2000 towards approval in the U.S. and other countries, an additional component of our strategy is to discover, develop and potentially commercialize a portfolio of compounds to treat orphan diseases and potentially, non-orphan diseases. Identifying new compounds requires substantial technical, financial and human resources, whether any other compounds are ultimately identified. We may not be able to identify new molecules with the potential for clinical development and ultimate approval. Even if we identify new compounds that initially show promise, we may fail to successfully develop and commercialize such new compounds for many reasons, including the following:

- the research methodology used may not be successful in identifying potential new compounds;
- competitors may develop alternatives that render our compounds obsolete;
- new compounds we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a new compound may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a new compound may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a new compound may not be accepted as safe and effective by patients, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional new compounds, our potential for growth may be impaired.

We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize CC8464 and CT2000.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any compound that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render CC8464 and CT2000 uneconomical or obsolete, and we may not be successful in marketing CC8464 and CT2000 against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any compound that we may develop and commercialize.

On December 23, 2023, we entered into the Benuvia License Agreement. We are dependent on the Benuvia License Agreement, and the termination of the Benuvia License Agreement could have an adverse effect on our business.

On December 23, 2023, we entered into the Benuvia License Agreement for the Diclofenac Spray Formulation, the Rizatriptan Spray Formulation and the Ondansetron Spray Formulation, diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The Diclofenac Spray Formulation is patented and has started clinical development in human volunteers. Preliminary pharmacokinetics suggest that this formulation may have a faster onset of action than oral Diclofenac tablets. Diclofenac is an NSAID that is also marketed under additional brand names including Voltaren and Cataflam in its pill form. Rizatriptan, whose brand name is Maxalt, is used for the acute treatment of migraines as a pill. Ondansetron is an anti-emetic that is available in oral and intravenous form. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations. If we breach the Benuvia License Agreement, Benuvia may be able to terminate it, and as a result of this termination, our business could be negatively impacted.

If Benuvia does not properly maintain or enforce the intellectual property underlying the Benuvia License Agreement, our competitive position and business prospects could be harmed. Benuvia may also seek to terminate our license.

We are a party to the Benuvia License Agreement. To this end, we are dependent on our license with Benuvia. Our success will depend in part on the ability of Benuvia to obtain, maintain and enforce its licensed intellectual property. Benuvia may not successfully prosecute any applications for or maintain intellectual property to which we have licenses, may determine not to pursue litigation against other companies that are infringing such intellectual property, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer similar products for sale, which could adversely affect our competitive business position and harm our business prospects. If we lose any of our right to use third-party intellectual property, it could adversely affect our ability to commercialize our technologies, products or services, as well as harm our competitive business position and our business prospects.

Rizatriptan is an off-patent branded generic that can be manufactured and sold by other pharmaceutical manufacturers, which may increase the competition we face and reduce our ability to diversify our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions under the Benuvia License Agreement.

Rizatriptan is an off-patent branded generic pharmaceutical and is currently not protected by intellectual property rights. As a result, other pharmaceutical companies may sell products similar to the Rizatriptan Spray Formulation at a lower cost, and this might result in a commensurate loss in expected sales or require us to lower our prices to compete. If other pharmaceutical companies sell products that are similar to the Rizatriptan Spray Formulation, we may face additional competition and our business and profitability may be adversely affected, and our ability diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions under the Benuvia License Agreement may be reduced.

Risks Related to Manufacturing

Delays in obtaining regulatory approvals of the process and facilities needed to manufacture CC8464, CT2000 or any of our other compounds or disruptions in our manufacturing process may delay or disrupt our product development and commercialization efforts.

Before we can begin to commercially manufacture CC8464, CT2000 or any of our other compounds, whether in a third-party facility or in our own facility, if established, we must pass a pre-approval inspection of our manufacturing facility by the FDA. A manufacturing authorization must also be obtained from the appropriate regulatory authorities. The timeframe required for us to obtain such approvals is uncertain. To obtain approval, we will need to ensure that all our processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any compound that we may develop.

In addition, the manufacturing process used to produce our existing compounds is complex, novel and has not been validated for commercial use. To produce enough quantities of our existing compounds for future clinical trials and initial U.S. commercial demand, we will need to increase the scale of our manufacturing process. We employ multiple steps to control our manufacturing process to assure that the process works and that CC8464 and CT2000 are made strictly and consistently in compliance with the process. Problems with, or deviations from, the manufacturing process, even if minor, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

Any contamination in our manufacturing process, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Given the nature of sterile product manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce CC8464 and CT2000 on schedule and could, therefore, harm our results of operations and cause reputational damage.

Some of the raw materials required in our manufacturing process may be derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of CC8464 and CT2000 could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Risks Related to Commercialization of Our Compounds

If we are unable to expand our market development capabilities or enter into agreements with third parties to market and sell our compounds, we may be unable to generate any revenue.

We currently do not have a market development organization. To successfully commercialize CC8464 and CT2000, if approved, we will need to expand our capabilities to promote market access and build awareness. To successfully commercialize any other products that may result from our development programs, we will need to further expand our market development organization, either on our own or with a third party. The development of our own market development team will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may enter into collaboration agreements regarding any of our compounds with third parties to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any future collaborators do not commit sufficient resources to commercialize our products, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded medical affairs, marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our compounds. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Our efforts to educate the medical community and third-party payors on the benefits of our compounds may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our potential products. If any of our compounds are approved but fails to achieve market acceptance among physicians, patients or third-party payors, we will not be able to generate significant revenues from such product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If the market opportunities for CC8464, CT2000 or our future compounds are smaller than we believe they are, our revenues may be adversely impacted, and our business may suffer.

We are currently focusing our research and product development efforts on CC8464 for the management of EM and iSFN and CT2000 for acute and chronic eye pain and, potentially, other fields of neuropathic pain. Our understanding of both the number of people who have EM or iSFN, as well as the subset of people with either disease who have the potential to benefit from treatment with CC8464, are based on estimates in published literature. Similarly, our understanding of the number of people who could benefit from treatment with CT2000, are based on estimates in published literature. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of this disease. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected or these patients may not be otherwise amenable to treatment with CC8464 and CT2000 or may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects.

Further, there are several factors that could contribute to making the actual number of patients who receive CC8464 and CT2000 less than the potentially addressable market. These include the increased use of currently available medication for mild cases as physicians gain a better understanding diagnosis and treatment of EM and iSFN, the discovery of novel medications for EM and iSFN and the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for CC8464 and CT2000, if approved, or any of our other future compounds that may be approved in the future, which would adversely affect our revenue and results of operations.

We expect that coverage and reimbursement of pharmaceutical costs may be increasingly restricted both in the U.S. and internationally. The escalating cost of health care has led to increased pressure on the health care industry to reduce costs. Drug pricing by pharmaceutical companies recently has come under increased scrutiny and continues to be subject to intense political and public debate in the U.S. and abroad. Government and private third-party payors have proposed health care reforms and cost reductions. A number of federal and state proposals to control the cost of health care, including the cost of drug treatments, have been made in the US. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. In some international markets, the government controls the pricing, which can affect the profitability of drugs. Current government regulations and possible future legislation regarding health care may affect coverage and reimbursement for medical treatment by third-party payors, which may render our compounds, if approved, not commercially viable or may adversely affect our anticipated future revenues and gross margins.

We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments. However, future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs generally could restrict the amount that we are able to charge for our future products, which would adversely affect our anticipated revenue and results of operations.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our products, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our compounds will depend substantially, both domestically and abroad, on the extent to which the costs of our compounds will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Coverage and reimbursement by a third- party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our compounds. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and government payors develop their coverage and reimbursement policies.

Outside the United States, international operations generally are subject to extensive government price controls and other market regulations and increasing emphasis on cost-containment initiatives in the European Union, Canada and other countries may put pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. It also can take a significant amount of time after approval of a product to secure pricing and reimbursement for such product in many counties outside the United States. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our compounds. Accordingly, in markets outside the United States, the reimbursement for our products will be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenues.

Moreover, increasing efforts by government and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our compounds. Payors increasingly are considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price, and Actual Acquisition Cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover candidate products that we or our partners are able to commercialize. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products such as ours.

Risks Related to Our Business Operations

We may not be successful in our efforts to identify or discover additional compounds and may fail to capitalize on programs or compounds that may be a greater commercial opportunity or for which there is a greater likelihood of success.

Beyond the development and commercialization of CC8464 and CT2000, the future success of our business depends upon our ability to identify, develop and commercialize compounds based on the platform technology. CC8464, and CT2000, from which it was derived, was discovered in our labs using our technologies. Research programs to identify new compounds will require to invest substantial technical, financial and human resources. We may fail to identify other potential compounds for clinical development for several reasons. For example, our research may be unsuccessful in identifying potential compounds or our potential compounds may be shown to have harmful side effects, may be commercially impracticable to manufacture or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or compounds or for indications that later prove to have greater commercial potential. Our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular compound, we may relinquish valuable rights to that compound through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such compound. Alternatively, we may allocate internal resources to a compound in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon our development efforts with respect to a particular compound or fail to develop a potentially successful compound, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to manage expected growth in the scale and complexity of our operations, our performance may suffer.

If we are successful in executing our business strategy, we will need to expand our managerial, operational, financial and other systems and resources to manage our operations, continue our research and development activities and, in the longer term, build a commercial infrastructure to support commercialization of any of our compounds that are approved for sale. Future growth would impose significant added responsibilities on members of management. It is likely that our management, finance, development personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and our compounds requires that we continue to develop more robust business processes and improve our systems and procedures in each of these areas and to attract and retain enough numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and growth goals.

Our future success depends on our ability to retain key employees and scientific advisors and to attract, retain and motivate qualified personnel.

Our success is dependent upon certain key management and technical personnel, the loss of whose services may adversely impact the achievement of our objectives. Our Chief Executive Officer, Chief Financial Officer, Chief Medical Officer, Treasurer and Corporate Secretary have played key roles in the founding, management, technology development and/or promotion of the Company. We currently do not hold key man insurance on our executives. Even if we do seek to obtain such insurance, we cannot assure you that such insurance will be available on acceptable terms or at all. The loss of the services of either our Chief Executive Officer, Chief Financial Officer, Chief Medical Officer, Treasurer or Corporate Secretary could have a material adverse effect on our business, financial condition, and results of operations.

We employ additional staff that are critical to implementing our clinical development and business strategy, and further development of our products will require that we recruit additional employees or consultants, particularly qualified scientific and technical personnel. Any inability to retrain and attract key employees or advisors may impede the progress of our research, development and commercialization objectives which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, failure to succeed in preclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel.

Our employees, principal investigators and advisors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and advisors. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained during clinical trials or interactions with the FDA or other regulatory authorities, which could result in criminal and civil penalties or sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines, criminal penalties, or other sanctions.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our current and future drug candidates.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approvals for CC8464 and CT2000 and begin commercializing them in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Anti-Kickback Statute, federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business as well as other jurisdictions. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. The ACA amended the intent requirement of the federal Anti-Kickback Statute to clarify that a person or entity does not have to have actual knowledge of this statute or specific intent to violate it;

- federal civil and criminal false claims laws and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent. The ACA provides that a claim for items or services resulting from an Anti-Kickback Statute violation is a false claim under the FCA. Cases against pharmaceutical manufacturers support the view that certain marketing practices, including off-label promotion, may implicate the FCA;

- HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);

- HIPAA, as amended by HITECH, and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under HITECH and the Genetic Information Nondiscrimination Act;

- other modifications to HIPAA, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers.

- federal transparency laws, including the federal Physician Payment Sunshine Act, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals and (ii) ownership and investment interests held by physicians and their immediate family members;

- state and foreign law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states; and

- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not enrollment by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the generation, handling, use, storage, treatment, manufacture, transportation and disposal of, and exposure to, hazardous materials and wastes, as well as laws and regulations relating to occupational health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biologic materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance for certain costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

We also may incur substantial costs to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including conditions that are outside of our control, such as the impact of health and safety concerns, including COVID-19 and the Omicron COVID-19 variant, as well as the recent inflation in the United States, foreign and domestic government sanctions imposed on Russia as a result of its invasion of Ukraine, war or other military conflict, terrorist activities, and other disruptions to global supply chains. Each of these events has caused or may continue to result in extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, whether due to inflationary pressures or otherwise, could result in a variety of risks to our business, including weakened demand for our compounds and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and financial condition and results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder.

Although we regularly assess our banking relationships and the location of the assets held in the company's account as we believe necessary or appropriate, our access to funding sources and other credit arrangements could be significantly impaired by factors that affect the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry.

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our compounds.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, COVID-19 surfaced in Wuhan, China and has since spread worldwide, including to New Jersey where our primary office and laboratory space is located. In response to the COVID-19 pandemic, we reduced staff and slowed down development activities as capital and testing options available to us were more limited. The extent to which COVID-19 will impact our future operations or those of our third-party partners, including our clinical trial operations, will also depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, adverse impacts of the Omicron COVID-19 variant or other COVID-19 variants, new information that will emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

The continued spread of COVID-19 globally could adversely impact our preclinical or clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19. COVID-19 may also affect employees of third-party CROs and CMOs located in affected geographies that we rely upon to carry out our clinical trials.

In addition, the patient populations that we target may be particularly susceptible to COVID-19, which may make it more difficult for us to identify patients able to enroll in our future clinical trials and may impact the ability of enrolled patients to complete any such trials. Any negative impact COVID-19 has to patient enrollment or treatment, or the execution of our compounds could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our compounds, increase our operating expenses, and have a material adverse effect on our financial results.

On May 11, 2023, the United States government declared an end to the COVID-19 pandemic, but the negative effects from COVID-19 described above may still be present for the foreseeable future.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures.

While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our compounds could be delayed.

Cyber-security incidents, including data security breaches or computer viruses, could harm our business by disrupting our delivery of services, damaging our reputation or exposing us to liability.

We receive, process, store and transmit, often electronically, confidential data of others. Unauthorized access to our computer systems or stored data could result in the theft or improper disclosure of confidential information, the deletion or modification of records, or could cause interruptions in our operations. These cyber-security risks increase when we transmit information from one location to another, including transmissions over the Internet or other electronic networks. Despite implemented security measures, our facilities, systems, and procedures, and those of our third-party service providers, may be vulnerable to security breaches, acts of vandalism, software viruses, misplaced or lost data, programming and/or human errors, or other similar events which may disrupt our delivery of services or expose the confidential information of our customers and others. Any security breach involving the misappropriation, loss or other unauthorized disclosure or use of confidential information of others, whether by us or a third party, could: (i) subject us to civil and criminal penalties; (ii) have a negative impact on our reputation; or (iii) expose us to liability to our customers, third parties or government authorities.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing, marketing and sale of human device and drug products. Product liability claims could delay or prevent completion of its development programs, clinical or otherwise. If we succeed in marketing and selling products, such claims could result in a recall of any products or a limitation or other change in the indications for which they may be used. If we cannot successfully defend ourselves against claims that our compounds or drugs caused injuries, we will incur substantial liabilities. Depending on their merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients.
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

In addition, we currently do not have product liability insurance, but plan to obtain such insurance at appropriate levels prior to initiating studies in humans or clinical trials and prior to marketing and selling any drug or device products. Any insurance we obtain may not provide sufficient coverage against potential liabilities. These liabilities could prevent or interfere with our product development and commercialization efforts. Furthermore, if we were unable or otherwise failed to obtain and maintain sufficient insurance at a reasonable cost to protect it against any such liabilities, that inability could have a material adverse effect on its business.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain adequate U.S. and foreign patent protection for our compounds, including CC8464 and CT2000, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technologies similar or identical to ours, and our ability to successfully commercialize CC8464, CT2000 and any of our other current or future compounds may be adversely affected.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to CC8464 and CT2000, additional new compounds in our product pipeline, and our institutional knowledge. The patent prosecution process is expensive, time- consuming and complex. In particular, we may not be able to file, prosecute, maintain, and/or enforce all necessary or desirable patent applications and issued patents at a reasonable cost or in a timely manner.

We have secured U.S. Patent No. 9,458,118 (the “CC8464 Patent”), covering the chemical composition and use of our clinical-stage NaV1.7 blocker. Apart from the CC8464 Patent, we have filed multiple patent applications in foreign jurisdictions, including Canada, France, India and Japan. It is possible that some of our pending patent applications in foreign jurisdictions will not result in issued patents in a timely fashion or at all, and even if we are granted the patents we are currently pursuing in foreign jurisdictions, the patents may not be issued in a form that will provide us with the full scope of protection that we desire, they may not prevent competitors or other third parties from competing with us, and/or they may not otherwise provide us with a competitive advantage. Our competitors, or other third parties, may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, there is no assurance that the CC8464 Patent, or any other patent that we may be granted, will prevent third parties from developing competing technologies. Moreover, our patent estate, including the CC8464 Patent, does not preclude third parties from obtaining intellectual property rights that could interfere with our freedom to use our platform for other indications. Even assuming patents issue from our pending and future patent applications, changes in either the patent laws or interpretation of the patent laws in the United States and foreign jurisdictions may diminish the value of our patents or narrow their scope of protection.

We may not be able to protect our intellectual property or enforce our intellectual property rights adequately throughout the world.

Filing and prosecuting patent applications on CC8464, CT2000 and future new compounds, current and future innovations related to our technology, and our institutional knowledge in all countries throughout the world would be prohibitively expensive, and intellectual property protections available in some countries outside the United States, and the enforceability thereof, may differ in scope from those in the United States. Thus, in some cases, we will not seek to obtain patent protection for certain technologies in some jurisdictions outside the United States. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our compounds, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting intellectual property and enforcing intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protections, particularly those relating to biotechnology products and those of foreign entities. Such challenges in enforcing rights in these countries could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our current and future patent rights in foreign jurisdictions could result in substantial costs and may divert our efforts and attention from other aspects of our business; could put our asserted patents at risk of being invalidated or interpreted narrowly; could put any future patent applications, including continuation and divisional applications, at risk of not issuing; and could provoke third parties to assert their own patent claims against us or to attack the validity of our other patents. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce any intellectual property rights around the world stemming from intellectual property that we develop may be inadequate to obtain a significant commercial advantage in these foreign jurisdictions.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability (and the ability of any potential future collaborators) to develop, manufacture, market and sell CC8464, CT2000 and future new compounds, and to freely use our proprietary technologies (*e.g.*, without infringing the intellectual property rights of others). Many companies and institutions have filed, and continue to file, patent applications related to various aspects of pain management and opioid sparing technology. Because patent applications can take many years to issue, may be confidential for 18 months or more after filing, and can be revised before and after issuance, there may be issued patents and patent applications now pending which may later result in issued patents that a third party asserts are infringed by the manufacture, use, sale, or importation of our products. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. Our competitors or other third parties may assert infringement claims against us, alleging that our therapeutics, manufacturing methods, formulations or administration methods are covered by their patents. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue, and against whom our patent portfolio may therefore have no deterrent effect.

Third parties may initiate legal or administrative proceedings attacking the validity of our patents protecting CC8464, CT2000 and future compounds the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to CC8464, CT2000 or any future compounds, or related technologies, including, for example, interference proceedings, post grant review challenges, and *inter partes* review before the USPTO. For example, a third party may bring an *inter partes* review challenging our patents and any future patent that may be granted to us. Such proceedings often are used as a tactic by defendants in a patent litigation suit to threaten a patentee's patents, both asserted in the litigation and unasserted. Thus, a competitor, either in response to litigation initiated by us or in the ordinary course, may threaten the validity, enforceability, and breadth of our patents which could have a negative impact on our business and render our patents or other intellectual property rights ineffective or insufficient to prevent competition.

Instituting and defending against patent and other types of intellectual property litigation and administrative proceedings could cause us to spend substantial resources, distract our personnel from their normal responsibilities, and have uncertain outcomes.

Patent and other types of intellectual property litigation and administrative proceedings can involve complex factual and legal questions, and their outcomes are uncertain. A finding of infringement could prevent us from manufacturing and commercializing our technologies, including CC8464 and CT2000, or force us to cease some or all our business operations. If we are found or believe there is a risk that we may be found, to infringe a third party's valid and enforceable intellectual property rights, we could be required (or may choose) to obtain a license from such a third party to continue developing, manufacturing and marketing our technologies. However, we may not be able to obtain any required license on commercially reasonable terms, if at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and further, it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technologies, including CC8464 and CT2000. We also could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Litigation or other legal or administrative proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming. Competitors may infringe our current or future patents, should such patents issue, or we may be required to defend against claims of infringement or other unauthorized use of third-party intellectual property or third-party attacks against our intellectual property rights. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property may cause us to incur significant expenses and could distract our scientific and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation despite our attempts to prevent such disclosure. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Common Stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating, or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Changes in United States patent law and its administrative and judicial interpretation could diminish the value of patents in general, thereby impairing our ability to protect our compounds.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. As patent reform legislation can inject serious uncertainty into the patent prosecution and litigation processes, it is not clear what impact future patent reform legislation will have on the operation of our business. However, such future legislation, and its implementation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Moreover, the patent positions of companies engaged in the development and commercialization of pharmaceuticals are particularly uncertain. We cannot assure you that our efforts to seek patent protection for CC8464, CT2000 and future new compounds will not be negatively impacted by the future court decisions or changes in guidance or procedures issued by the USPTO. These decisions, and any guidance issued by the USPTO (or changes thereto), could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property rights in the future.

Intellectual property rights and regulatory exclusivity rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our current and future new compound but that are not covered by the claims of our current patents or of patents that we may own or license in the future;

- we, or any future license partners or collaborators, might not have been the first to file patent applications covering certain aspects of the concerned technologies;

- others may independently develop similar or alternative technologies, or duplicate any of our technologies, potentially without falling within the scope of our current or future issued claims, thus not infringing our intellectual property rights;
- it is possible that our filed or future patent applications will not lead to issued patents;
- issued patents to which we currently hold rights or to which we may hold rights in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- others may have access to any future intellectual property rights licensed to us on a non-exclusive basis;
- our competitors might conduct research and development activities in countries where we have or intend to pursue patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets where we do not have patent rights;
- we may not develop additional proprietary technologies that are patentable;
- the patents or other intellectual property rights of others may have an adverse effect on our business; and
- we may choose not to file a patent application covering certain of our trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

In addition to patent protection, we also rely on the protection of trade secrets, know-how and confidential and proprietary information. The disclosure of our trade secrets would impair our competitive position and could harm our business. However, trade secrets are difficult to protect. To maintain the confidentiality of trade secrets and proprietary information, we rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and/or other advisors, and inventions agreements with employees, consultants, and advisors, to protect our trade secrets and other proprietary information. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees and consultants also provide that inventions conceived by the individual in the course of rendering services to us will be our exclusive property. Despite these efforts, we cannot provide any assurances that these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information.

In the event of unauthorized use or disclosure of trade secrets or proprietary information, these agreements, even if obtained, may not provide sufficient protection for our trade secrets or other confidential information. Further, to the extent that our employees, consultants or contractors use technology or know-how owned by others in their work for the Company, disputes may arise as to the rights in related inventions. This can be of particular concern with respect to university collaborators with us, who typically have pre-existing obligations to their universities to assign intellectual property rights, which university rights generally are superior to assignment rights that we might receive from such individuals.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and/or consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Risks Related to our Common Stock

The market price and trading volume of our shares of Common Stock may experience rapid and substantial price volatility, which could cause purchasers of our Common Stock to incur substantial losses.

Recently, the market prices and trading volume of shares of Common Stock of other small publicly traded companies with a limited number of shares available to purchasers, have experienced rapid and substantial price volatility unrelated to the financial performance of those companies. Similarly, shares of our Common Stock may experience similar rapid and substantial price volatility unrelated to our financial performance, which could cause purchasers of our Common Stock to incur substantial losses, which may be unpredictable and not bear any relationship to our business and financial performance. Extreme fluctuations in the market price of our Common Stock may occur in response to strong and atypical retail investor interest, including on social media and online forums, the direct access by retail investors to broadly available trading platforms, the amount and status of short interest in our Common Stock and our other securities, access to margin debt, trading in options and other derivatives on our shares of Common Stock and any related hedging and other trading factors.

If there is extreme market volatility and trading patterns in our Common Stock, it may create several risks for investors, including the following:

- the market price of our Common Stock may experience rapid and substantial increases or decreases unrelated to our operating performance or prospects, or macro or industry fundamentals;
- if our future market capitalization reflects trading dynamics unrelated to our financial performance or prospects, purchasers of our Common Stock could incur substantial losses as prices decline once the level of market volatility has abated;
- if the future market price of our Common Stock declines, purchasers of shares of Common Stock may be unable to resell such shares at or above the price at which they acquired them. We cannot assure such purchasers that the market of our Common Stock will not fluctuate or decline significantly in the future, in which case investors could incur substantial losses.

Further, we may incur rapid and substantial increases or decreases in our Common Stock price in the foreseeable future that may not coincide in timing with the disclosure of news or developments by or affecting us. Accordingly, the market price of our Common Stock may fluctuate dramatically, and may decline rapidly, regardless of any developments in our business. Overall, there are various factors, many of which are beyond our control, that could negatively affect the market price of our Common Stock or result in fluctuations in the price or trading volume of our Common Stock, including:

- actual or anticipated variations in our annual or quarterly results of operations, including our earnings estimates and whether we meet market expectations with regard to our earnings;

- our current inability to pay dividends or other distributions;
- publication of research reports by analysts or others about us or the industry in which we operate, including the pharmaceutical or biotechnology industry which may be unfavorable, inaccurate, inconsistent or not disseminated on a regular basis;
- changes in market valuations of similar companies;
- market reaction to any additional equity, debt or other securities that we may issue in the future, and which may or may not dilute the holdings of our existing stockholders;
- additions or departures of key personnel;
- actions by institutional or significant stockholders;
- short interest in our Common Stock or our other securities and the market response to such short interest;
- the dramatic increase in the number of individual holders of our Common Stock and their participation in social media platforms targeted at speculative investing;
- speculation in the press or investment community about our company or industries in which we operate;
- strategic actions by us or our competitors, such as acquisitions or other investments;
- legislative, administrative, regulatory or other actions affecting our business, our industry, including positions taken by the FDA;
- investigations, proceedings, or litigation that involve or affect us;
- the occurrence of any of the other risk factors included in this Report; and
- general market and economic conditions.

Our Common Stock is currently listed on NYSE American. NYSE American may delist our Common Stock from trading, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

Should we fail to satisfy the continued listing requirements for remaining listed on NYSE American, such as the corporate governance requirements or the minimum closing bid price requirement, NYSE American may take steps to delist our Common Stock. Such a delisting would likely have a negative effect on the price of our Common Stock and would impair your ability to sell or purchase our Common Stock when you wish to do so. In the event of a delisting, we would take actions to restore our compliance with NYSE American's listing requirements, but we can provide no assurance that any such action taken by us would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our Common Stock, prevent our Common Stock from dropping below NYSE American's minimum bid price requirement or prevent future non-compliance with such listing requirements.

If we cannot maintain the listing of our Common Stock for trading on NYSE American, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our Common Stock;
- reduced liquidity for our Common Stock;

- a determination that our Common Stock is a “penny stock” which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our Common Stock;

- a limited amount of news and analyst coverage; and

- a decreased ability to issue additional Common Stock or obtain additional financing in the future.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our board of directors;

- limit the manner in which stockholders can remove directors from the board;

- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;

- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;

- limit who may call stockholder meetings;

- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware (the “DGCL”), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation and our bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation and our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Notwithstanding the foregoing, the exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive or concurrent jurisdiction. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act of the rules and regulations thereunder, and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder, and notwithstanding the provisions of our certificate of incorporation and our bylaws, compliance with the federal securities laws and the rules and regulations thereunder may not be waived by our investors. The choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation and our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition, and results of operation.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our Common Stock to drop significantly, even if our business is performing well.

Sales of substantial amounts of our shares of Common Stock in the public market following the IPO, or the perception that these sales could occur, could cause the market price of our securities to decline. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

All of the shares of Common Stock in the IPO are immediately tradable without restriction under the Securities Act, except for any securities held by "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144.

The remaining shares of Common Stock of the Company outstanding, other than the 2,969,823 shares (the "Selling Stockholder Shares") of Common Stock that we have registered on behalf of certain selling stockholders (the "Selling Stockholders") identified in a separate prospectus (the "Resale Prospectus") and which may be resold by such Selling Stockholders from time to time, are restricted securities within the meaning of Rule 144 under the Securities Act but will be eligible for resale subject to applicable volume, means of sale, holding period and other limitations of Rule 144 under the Securities Act or pursuant to an exception from registration under Rule 701 under the Securities Act, subject to the lock-up agreements executed in conjunction with the IPO.

In addition, we have registered the Selling Stockholder Shares pursuant to the Resale Prospectus and, as a result, all of the Selling Stockholder Shares are freely tradable under the Securities Act, subject to the terms of the lock up agreements.

We intend to file one or more registration statements on Form S-8 under the Securities Act to register the shares of Common Stock to be issued under our equity compensation plans and, as a result, all shares of Common Stock acquired under our plans will also be freely tradable under the Securities Act, subject to the terms of the lock-up agreements, unless purchased by our affiliates. In addition, 444,444 shares of our Common Stock will be reserved for future issuances under the equity incentive plan that we have adopted.

In connection with the Bridge Financings (defined below), we are required to file a registration statement within 180 calendar days after the consummation of the IPO, providing for the resale of Common Stock, which includes 549 Bonus Shares (as defined below), received by holders of the senior secured convertible notes upon conversion of such notes.

In connection with our proposed ELOC, we intend to file a registration statement, providing for the resale of the shares of Common Stock issuable pursuant to the proposed ELOC, if issued. An agreement with respect to our proposed ELOC has not been, and may never be, finalized and executed and there is no assurance that we will enter into an ELOC or, if we do enter into such an ELOC, that the terms thereof will be consistent with or as favorable as those described in this Report.

In the future, we may issue additional shares of Common Stock or other equity or debt securities convertible into Common Stock in connection with draw-downs under our proposed ELOC, a financing, acquisition, litigation settlement or employee arrangement or otherwise. Any of these issuances could result in substantial dilution to our existing stockholders and could cause the trading price of our securities to decline.

The Series C Preferred Stock has a liquidation preference over our Common Stock.

The Series C Preferred Stock has a liquidation preference that gets paid prior to any payment on our Common Stock. As a result, if we were to liquidate, dissolve or wind-up, each holder of our Series C Preferred Stock would have the right to receive payment out of our assets available for distribution, before any amount is paid to the holders of our Common Stock, in an amount in cash equal to the aggregate liquidation value of all of the shares of preferred stock held by such holder. Holders of the Series C Preferred Stock will not be entitled to dividends. The payment of the liquidation preferences on the Series C Preferred Stock could result in holders of our Common Stock not receiving any proceeds if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily.

The existence of the liquidation preferences may reduce the value of our Common Stock, make it harder for us to sell shares of Common Stock in offerings in the future, or prevent or delay a change of control.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our Common Stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. If securities analysts do not commence coverage of us, the trading price of our stock could decrease. Additionally, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

The price of our securities may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our securities.

The market price of our securities is likely to be highly volatile due to many factors, including:

- our ability to successfully proceed to and conduct clinical trials;
- results of pre-clinical and clinical trials of our existing lead or new future compounds or those of our competitors;
- the success of competitive products or technologies;
- commencement or termination of collaborations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our current or future compounds or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional new compounds;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;

- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

The stock markets have experienced extreme volatility in recent years that has been unrelated to operating performance. These broad market fluctuations may adversely affect the trading price of our securities. In the past, following periods of volatility in the market price of a company’s securities, class action litigation has often been instituted against the affected company. Any litigation of this type brought against us could result in substantial costs and a diversion of our management’s attention and resources, which would harm our business, results of operations, financial condition and cash flows.

We have broad discretion in the use of our cash, including the net proceeds from the IPO, and may not use them effectively.

Our management will have broad discretion in the application of our cash, including the net proceeds from the IPO, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our Common Stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our Common Stock to decline and delay the development of CC8464, CT2000 and any other new compounds that we may develop. Pending their use, we may invest our cash, including the net proceeds from the IPO, in a manner that does not produce income or that loses value.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies, CC8464 or CT2000.

We may seek additional capital through a combination of draw-downs under our proposed ELOC, public and private equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, CC8464 or CT2000 or grant licenses on terms unfavorable to us.

We are an “emerging growth company” and the reduced disclosure requirements applicable to emerging growth companies may make our Common Stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not “emerging growth companies.” In particular, while we are an “emerging growth company: (i) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act; (ii) we will be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor’s report on financial statements; (iii) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved. Investors may find our Common Stock less attractive if we rely on the exemptions and relief granted by the JOBS Act. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may decline or become more volatile.

We have taken advantage of reduced reporting burdens in this Report. We cannot predict whether investors will find our Common Stock less attractive if we rely on certain or all of these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We will incur increased costs as a result of operating as a smaller reporting public company, and our management will be required to devote substantial time to new compliance initiatives.

As a smaller reporting public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and NYSE American have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.

Risks Related to our Proposed ELOC

There is no assurance that we will enter into our proposed ELOC or that the terms thereof will be consistent with or as favorable as those described in this Report.

We anticipate that we will enter into a purchase agreement to issue the shares of Common Stock issuable pursuant to the ELOC; however, as of the date hereof, an agreement with respect to our proposed ELOC has not been, and may never be, finalized and executed and there is no assurance that we will enter into an ELOC or, if we do enter into such an ELOC, that the terms thereof will be consistent with or as favorable as those described in this Report.

Issuances of our Common Stock to the Holder of the Investor Note under our proposed ELOC may have a significant dilutive effect.

We are negotiating an arrangement with the Holder of the Investor Note to enter into a proposed ELOC, pursuant to which we will have the right, but not the obligation, to sell to the Holder of the Investor Note up to $20,000,000 in newly issued shares of our Common Stock, subject to certain limitations. Depending on the number of shares of Common Stock we issue to the Holder of the Investor Note pursuant to the proposed ELOC, it could have a significant dilutive effect upon our existing stockholders. Although the number of shares of Common Stock that we may issue pursuant to the proposed ELOC will vary based on our stock price (the higher our stock price, the fewer shares of our Common Stock we have to issue), there may be a potential dilutive effect to our stockholders, based on different potential future stock prices, if the full amount of the proposed ELOC is realized. Dilution is based upon shares of Common Stock "put" to the Holder of the Investor Note and the stock price discounted to the Holder of the Investor's purchase price of 95% of the lowest volume-weighted average price during the three (3) consecutive trading days immediately following our notice to the Holder of the Investor Note of our exercise of our "put" right, with the lesser of (i) one hundred percent (100%) of the average daily trading volume over the five days before our notice to the Holder of the Investor Note, (ii) forty percent (40%) of the daily trading volume on the date of our notice to the Holder of the Investor Note or (iii) $2,000,000, delivered in shares of our Common Stock for each particular "put".

Our existing stockholders may experience significant dilution from the sale of our shares of Common Stock pursuant to our proposed ELOC.

The sale of our Common Stock to the Holder of the Investor Note in accordance with the proposed ELOC may have a dilutive impact on our stockholders. As a result, the market price of our Common Stock could decline. In addition, the lower our stock price is at the time we exercise our put options, the more shares of our Common Stock we will have to issue to the Holder of the Investor Note in order to exercise a put under the proposed ELOC. If our stock price decreases, then our existing stockholders would experience greater dilution for any given dollar amount raised through the proposed ELOC.

The perceived risk of dilution may cause our stockholders to sell their shares, which may cause a decline in the price of our Common Stock. Moreover, the perceived risk of dilution and the resulting downward pressure on our stock price could encourage investors to engage in short sales of our Common Stock. By increasing the number of shares offered for sale, material amounts of short selling could further contribute to progressive price declines in our Common Stock.

We may not have access to the full amount available under our proposed ELOC.

Under our proposed ELOC, we will have the right to direct the Holder of the Investor Note to purchase shares of our Common Stock from time to time by presenting the Holder of the Investor Note with a purchase notice directing it to purchase shares according to the terms of the related purchase agreement.

Although, pursuant to our proposed ELOC, we may sell up to $20,000,000 in shares of our Common Stock to the Holder of the Investor Note, depending on the market prices of our Common Stock, we may not be able to nor desire to sell all of the shares of Common Stock contemplated by our proposed ELOC. In addition, we will be required to file one or more additional registration statements to register any shares issued under our proposed ELOC.

The extent to which we rely on the Holder of the Investor Note as a source of funding will depend on a number of factors, including the prevailing market price of our Common Stock and the extent to which we are able to secure working capital from other sources. Even if we sell a significant amount of shares under our proposed ELOC to the Holder of the Investor Note, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, liquidity, financial condition and prospects.

The Holder of the Investor Note will pay less than the then-prevailing market price for shares of our Common Stock, which could cause the price of our Common Stock to decline.

The purchase price of Common Stock sold to the Holder of the Investor Note under our proposed ELOC will be 95% of the lowest volume-weighted average price during the three (3) consecutive trading days immediately following our notice to the Holder of the Investor Note of our exercise of our "put" right. Therefore, shares of Common Stock to be sold to the Holder of the Investor Note pursuant to our proposed ELOC will be purchased at a discounted price as described above. As a result of this pricing structure, the Holder of the Investor Note has a financial incentive to sell our shares of Common Stock immediately upon receiving them to realize the profit between the discounted price and the market price, subject to certain limitations. If the Holder of the Investor Note sells our shares of Common Stock, the price of our Common Stock may decrease. If our Common Stock price decreases, the Holder of the Investor Note may have further incentive to sell such shares. Accordingly, the discounted sales price in our proposed ELOC may cause the price of our Common Stock to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Risk management and strategy

We are an R&D stage pharmaceutical company, with no commercial operations or revenue streams. Since our IPO, our sole business activity has been ongoing research into our drug therapies]. Therefore, we do not consider that we face significant cybersecurity risk and have not adopted a formal cybersecurity risk management program or process for assessing cybersecurity risk currently. We assess material risks from cybersecurity threats on an ongoing basis, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein. As our Company grows, we plan to develop a more robust and detailed strategy for cybersecurity in alignment with nationally accepted standards. We have not encountered cybersecurity challenges that have materially impaired our operations or financial standing. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, "Risk Factors," in this Annual Report on Form 10-K.

Governance

Our management and board of directors recognize the critical importance of maintaining the trust and confidence of our business partners and employees, including the importance of managing cybersecurity risks as part of our larger risk management program. While all of our personnel play a part in managing cybersecurity risks, one of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks that we face. In general, we seek to address cybersecurity risks through a cross-functional approach that is focused on preserving the confidentiality, integrity, and availability of the information that we collect and store by identifying, preventing, and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Item 2. Properties.

Our principal executive offices are located at 4400 Route 9 South, Suite 1000, Freehold, NJ 07728. The lease for our principal executive offices is on a month-to-month basis. We believe our executive offices are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space to support our operations and regulatory needs. We believe appropriate alternative space will be readily available on commercially reasonable terms.

Item 3. Legal Proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of our management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputation harm, and other factors.

On February 14, 2024, our board of directors received a demand letter from an attorney representing Chromocell Holdings and our former Chief Executive Officer and former Chief Strategy Officer, Mr. Christian Kopfli, who was released for "cause" as disclosed elsewhere in this Report. Mr. Kopfli alleges an improper termination for "cause" and seeks monetary damages in connection therewith in the amount of $479,169. Of the $479,169 asserted by Mr. Kopfli, as of December 31, 2023, the Company has accrued $363,091 in compensation expenses associated with Mr. Kopfli's prior employment with the Company. To the extent Mr. Kopfli is successful in his assertions, we will pay any amounts owed thereunder from future working capital reserves; however, we believe the assertions made by Mr. Kopfli are without merit and intend to vigorously defend the matter.

On April 9, 2024, we received correspondence notifying us of an Entry of Default Notice, filed on April 8, 2024, against "Chromocell Corporation d/b/a Chromocell Therapeutics" in the matter *New Jersey Economic Development Authority v. Chromocell Corporation, et al.* (Docket No. MER-L-001748-23). The complaint filed by the New Jersey Economic Development Authority (the "EDA") on September 12, 2023 in the Superior Court of New Jersey Law Division, Mercer County, alleges Chromocell Holdings' (not the Company's) breach of a Settlement Agreement between the EDA and Chromocell Holdings, dated December 31, 2022 (the "Settlement Agreement"), pursuant to which EDA and Chromocell Holdings agreed that Chromocell Holdings would (i) vacate the premises located at 671 US Highway One South, North Brunswick, New Jersey, on or before December 31, 2023, (ii) pay an initial lump-sum payment of $10,000 toward outstanding rent and provide a copy of its IPO Registration Statement and (iii) make a final one-time lump sum payment to the EDA of $510,700.62 to satisfy Chromocell Holdings' outstanding rent and additional rent obligations within 90 days of Chromocell Holdings' executing the Settlement Agreement or within 15 days of Chromocell Holdings' IPO, whichever was the first to occur. The complaint alleges Chromocell Holdings' breach of each of these provisions of the Settlement Agreement and sought a judgment for the entire amount due and owing as of September 12, 2023 ($510,700.62), compensatory damages, pre-judgment interest, attorney's fees, costs of suit and such other and further relief as the court deems just and proper. Besides including "Chromocell Therapeutics" in the case caption, the complaint does not include allegations related to any action purportedly taken by the Company. While the complaint appears to concern a matter between Chromocell Holding and EDA, the Company steadfastly believes it was inappropriately named as a defendant and intends to file a motion to vacate the Entry of Default and have "Chromocell Therapeutics" dismissed from the matter.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our Common Stock trades on NYSE American under the symbol "CHRO."

Holders of our Common Stock

As of April 10, 2024, there were approximately 23 holders of record of our Common Stock. This number does not include shares of Common Stock held by brokerage clearing houses, depositories or others in unregistered form.

Dividends

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our Common Stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Reference is made to "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters—Securities Authorized for Issuance under Equity Compensation Plans" for the information required by this item.

Use of IPO Proceeds

We completed our IPO in February 2024, pursuant to a registration statement on Form S-1, which was declared effective by the SEC on February 14, 2024 (File No. 333-269188) (the "Registration Statement"). Below are details of the Company's use of the IPO proceeds through the end of the reporting period, as required by Item 701(f) of Regulation S-K:

- A.G.P./Alliance Global Partners served as the sole book running manager in the offering of an aggregate of 1,100,000 shares of Common Stock to investors, which closed on February 21, 2024. Additionally, pursuant to such Registration Statement, an additional 2,969,823 Selling Stockholder Shares were registered for the resale of the Selling Stockholders listed on the Resale Prospectus forming a part of such Registration Statement, however the Company did not, and will not in the future, receive any proceeds from the registration of the offer and resale of such Selling Stockholder Shares.

- The title of the class of securities registered was the Common Stock.

- 1,100,000 shares of Common Stock were issued at a price of $6.00 per share for a total of $6,600,000 in gross proceeds.

- Total fees paid to underwriters in connection with the IPO were $0.5 million. Other fees incurred in connection with the issuance and distribution of the Common Stock between the effective date and the ending date of the reporting period include approximately $0.9 million in other offering expenses, such as listing expenses, fees for printing, advisory services, and SEC and other fees paid to regulators. These accrued expenses were deducted directly from paid-in capital. Net proceeds from the IPO after underwriting fees were $5.7 million, net of offering document expenses.

- Upon completion of the IPO, net proceeds were used for (i) to prepare and conduct a dose escalation study for CC8464 in an effort to establish a safe dose escalation regime; (ii) for in vivo and toxicology studies of CT2000 for the treatment of eye pain; (iii) for studies of CC8464 for the treatment of neuropathic pain; (iv) to prepare and begin conducting a Phase 2a POC study of CC8464 for EM or iSFN; (v) to determine market strategy and develop clinical programs for the Spray Formulations licensed from Benuvia; and (vi) to repay amounts outstanding under certain promissory notes.

- Except as set forth in the Registration Statement, in connection with the IPO, there were no direct or indirect payments to directors, officers, general partners of the issuer or their associates, or to persons owning 10 percent or more of any class of equity.

Recent Sales of Unregistered Securities

Pursuant to that certain Contribution Agreement entered into with Chromocell Holdings, we issued to Chromocell Holdings 1,111,111 shares of Common Stock and 600,000 shares of Series A Convertible Preferred Stock (the "Series A Preferred Stock").

On January 10, 2023, pursuant to the Chromocell Therapeutics Corporation 2023 Equity Incentive Plan (the "2023 Plan"), we granted: (a) options to purchase up to an aggregate of 141,667 shares of Common Stock to employees and directors and (b) 16,667 restricted stock units ("RSUs") to employees. The RSUs were cancelled on June 23, 2023 and as they had not vested, no expense was recorded on the Company's historical financial statements.

On March 9, 2023, pursuant to the 2023 Plan, we granted to a director options to purchase up to an aggregate of 15,000 shares of Common Stock.

On June 23, 2023, pursuant to that certain June Investor Note Side Letter (as defined below), we issued 5,556 shares of Common Stock to the Holder of the Investor Note.

On June 23, 2023, pursuant to the 2023 Plan, we granted to two employees options to purchase up to an aggregate of 52,000 shares of Common Stock, which include options that have not yet been granted but the Company has agreed to grant in connection with the closing of the offering of shares registered in the IPO (the "IPO Shares").

On August 17, 2023, pursuant to that certain August Investor Note Side Letter (as defined below), we issued 3,334 shares of Common Stock to the Holder of the Investor Note.

Effective October 10, 2023, pursuant to that certain October Investor Note Side Letter (as defined below), we issued 3,334 shares of Common Stock to the Holder of the Investor Note.

Effective November 13, 2023, pursuant to that certain November Investor Note Side Letter (as defined below), we agreed to issue 3,334 shares of Common Stock to the Holder of the Investor Note (as defined below) on each of November 29, 2023, December 29, 2023 and January 29, 2024, provided the Investor Note remained outstanding as of such date.

On December 1, 2023, we issued 2,442,469 shares of Common Stock in connection with our Rights Offering (as defined below), after giving effect to the Representative Affiliate Transactions (as defined below).

On December 23, 2023, in connection with the Benuvia License Agreement, we issued 384,226 shares of Common Stock to Benuvia pursuant to the Benuvia Stock Issuance Agreement (as defined below).

Effective January 30, 2024, pursuant to that certain January Investor Note Side Letter (as defined below), we agreed to issue 77,778 shares of Common Stock on the earlier to occur of the IPO or February 29, 2024.

The offers and sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the above securities represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing in this Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotech company focused on developing and commercializing new therapeutics to alleviate pain. Our clinical focus is to selectively target the sodium ion-channel known as "NaV1.7", which has been genetically validated as a pain receptor in human physiology. A NaV1.7 blocker is a chemical entity that modulates the structure of the sodium-channel in a way to prevent the transmission of pain perception to the CNS. Our goal is to develop a novel and proprietary class of NaV blockers that target the body's peripheral nervous system.

We have formally launched two programs developing pain treatment therapeutics, both based on the same proprietary molecule, as follows:

Neuropathic Pain: CC8464 is being developed to address certain types of neuropathic pain. The chemical characteristics of CC8464 restrict its entry into the CNS and limit its effect to the NaV1.7 receptors in the peripheral nervous system, which consists of the nerves outside the brain and spinal cord. Activation of other receptors in the CNS can result in side effects, including addiction and other centrally mediated adverse effects. Since CC8464 is designed to not penetrate the CNS it is highly unlikely to produce CNS mediated side effects including euphoria or addiction. Based on its characteristics, preclinical studies (described below) and the Phase 1 studies we have completed to date, we believe that CC8464, if approved, could become an attractive option for both patients and physicians as a treatment for moderate-to-severe pain in EM and iSFN.

We conducted four Phase 1 trials with 207 patients. The results showed that CC8464 has a good overall tolerability and demonstrated no liver or renal toxicity, no central nervous system changes and no cardiovascular findings but may cause rashes in certain patients. The occurrence of rashes is not uncommon in the class of molecules to which CC8464 belongs and the rashes were resolved in all cases with topical steroids and/or topical antihistamines (with the exception of one patient requiring systemic steroids).

As a result of the potential for rashes, following discussions with the FDA, we decided to launch a slow dose escalation study to further evaluate the incidence of rashes. By titrating the dose over nine weeks, we anticipate that we will reduce or eliminate this side effect. We expect that the slow dose escalation study will also help determine the need for dose escalation in the final treatment regime. Even though the FDA has in the past approved drugs that listed rashes as a potential side effect, we do not know if CC8464 will be approved by the FDA (or any foreign authority).

We anticipate that the dose escalation will enroll the first patient dosing in the third quarter of 2024. The dose escalation trial will enroll approximately 20 healthy volunteers who will receive CC8464 over a period of approximately nine weeks, with the dose escalation study expected to take approximately nine months in total. We anticipate that the slower dose escalation will decrease the likelihood of drug-related skin reactions. The primary endpoint of the dose escalation trail will be safety and tolerability of the slower dose titration; however, we will also be measuring blood concentrations of CC8464, which will allow us to better understand the pharmacokinetics of CC8464. Even if it is ultimately determined that we will need an escalation period for chronic pain treatment therapy, which patients could well take for the remainder of their lives, we do not believe the dose escalation approach is consequential.

We are conducting the escalation trial in Australia to avail ourselves of a 43.5% tax credit for clinical expenses incurred in Australia. The location of the POC has not been determined at this time, with availability of facilities and patient population, costs, tax credits, centers of excellence in the respective fields (EM or iSFN) are all factors in the ultimate determination of the location.

We are currently working on the development of the Phase 2a POC plan and expect to launch the Phase 2a POC study in 2025 to assess the potential efficacy of CC8464 in EM and iSFN patients. Both are orphan indications for which we plan to apply for orphan drug designations. The orphan indication may decrease the scope of the ultimate development program that is necessary for approval and is associated with a marketing exclusivity period from the FDA along with some tax advantages.

Though the Phase 2a POC study design has not yet been completed, the study will take approximately twelve months after it is initiated. The primary endpoint will be the amount of pain experienced from EM or iSFN with secondary endpoints including other measurements like pain relief and neuropathy scores. The final design may change based on feedback from regulatory authorities or information learned during the dose escalation trial.

The potential population for EM in the United States is estimated to be between 5,000 and 50,000 patients and the potential population for ISFN in the United States is estimated to be between 20,000 and 80,000 patients. In both instances, we expect patients would potentially take our drug for the remainder of their lives, and given the lack of good therapeutic alternatives, we expect to have a robust, ongoing, and durable market.

The Phase 2a results will have significance beyond EM and iSFN and provide important insights about NaV1.7 as a potential target to find novel pain medications as an alternative to opioids, the continuing primary standard of care in analgesics. We believe that positive results from the Phase 2a study could not only act as support for CC8464's potential in EM and iSFN but may also provide guidance of its potential for other indications of peripheral neuropathic pain.

Eye Pain: Based on the same proprietary molecule as CC8464, our newly launched program, titled CT2000, is for the potential treatment of both acute and chronic eye pain. NaV1.7 receptor is present on the cornea, making it a viable biological target for treating eye pain. Eye pain may occur with various conditions, including severe dry eye disease, trauma and surgery. Existing therapies for eye pain (such as steroids, topical non-steroidal anti-inflammatory agents, lubricants, local anaesthetics) are limited in their effectiveness and/or limited in the duration that they may be prescribed because of safety issues. We intend to explore the viability of developing CT2000 as a topical agent for the relief of eye pain. A potential advantage of this approach is that topical administration of CT2000 is unlikely to lead to any hypersensitivity or skin reactions, like what was noted with systemic administration of CC8464, because the systemic absorption from a topical administration would be extremely limited. We have commenced development of a topical ophthalmic formulation of CT2000 that would initially be evaluated for ophthalmic toxicology and then followed by a POC trial in patients. We expect the trials for this ophthalmic formulation of CT2000 to start in 2025.

Current options for the treatment of ocular pain center on the use of corticosteroids and NSAID based therapeutics. These options suffer from sight-threatening complications such as Glaucoma and corneal melting, thus there is a large unmet need for other approaches. As an example of the potential patient population, we estimate that there are approximately 5 million cases of corneal abrasions per year in the United States. In addition, other potential indications associated with eye pain include:

- severe dry eye,
- side effects from photorefractive keratectomy (PRK) and pterygium surgery,
- second eye cataract surgery,
- neuropathic corneal pain, and
- severe uveitis and severe iritis/scleritis.

As the NaV1.7 receptor is present on the cornea and is a viable biological target for treating eye pain, we believe that we have a sound scientific basis for our ability to treat a multitude of eye pain indications. We are in the process of formulating CT2000 eye drops and expect to move into animal toxicity studies in the second half of 2024. From there, we intend to move into proof-of-concept studies in humans.

We may further expand our pipeline with other internal or external compounds in the future, but all other internally discovered compounds are pre-clinical and no commercial discussions about in-licensing have been initiated to date, other than as disclosed in this Report with respect to the licensing of the "Spray Formulations.

We were incorporated in Delaware on March 19, 2021. On August 10, 2022, we entered into the Contribution Agreement with Chromocell Holdings. Pursuant to the Contribution Agreement, as of the Contribution Date, we acquired from Chromocell Holdings all assets, liabilities and results of operations related to Chromocell Holdings' therapeutic business, including all patents, pre-clinical and Phase I study results and data, and trade secrets related to the CC8464 compound, in exchange for the issuance by us of 1,111,112 shares of Common Stock and (ii) 600,000 shares of Series A Preferred Stock.

Prior to the Contribution Date, we had only nominal assets and liabilities. Accordingly, the financial statements presented in this Report for periods prior to the Contribution Date have been prepared on a "carve-out" basis from the financial statements of Chromocell Holdings to represent our financial position and performance as if it had existed on a stand-alone basis. The financial statements presented in this Report for periods from and after the Contribution Date reflect our financial position and performance as a stand- alone entity.

All of the assets, liabilities and results of operations of the Company as of and for the periods prior to the Contribution Date were identified based on the assets acquired by the Company from Chromocell Holdings. Management believes the assumptions underlying the Company's carve-out financial statements are reasonable. Nevertheless, the financial statements may not include all of the actual expenses that would have been incurred had the Company operated as a standalone company during the periods presented, and may not reflect the Company's results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Actual costs that would have been incurred if the Company had operated as a standalone company would depend on multiple factors, including organizational structure and strategic decisions made in various areas, including information technology and infrastructure.

On August 2, 2023, we entered into a Side Letter to the Contribution Agreement with Chromocell Holdings (the "Holdings Side Letter"). Pursuant to the Holdings Side Letter, upon closing of the IPO: (a) Chromocell Holdings re-assumed all $1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings waived the Company's obligations to make a cash payment in the amount of $0.6 million to Chromocell Holdings, and (c) in consideration thereof, we issued to Chromocell Holdings 2,600 shares of Series C Preferred Stock.

On February 21, 2024, we completed the IPO and issued and sold 1,100,000 shares of Common Stock at a price to the public of $6.00 per share. The aggregate net proceeds from the IPO were approximately $5.7 million after deducting underwriting discounts and commissions of approximately $0.5 million and offering expenses of approximately $0.4 million.

In connection with the completion of the IPO: (A) we have effected the 1-for-9 reverse stock split (the "Reverse Stock Split") of our shares of Common Stock, (B) all 600,000 issued and outstanding shares of our Series A Preferred Stock automatically converted into 499,429 shares of Common Stock, (C) $389,757 and accrued interest of approximately $28,336 as of February 21, 2024 outstanding under our senior secured convertible notes issued in the April Bridge Financing (as defined below) after giving effect to the Representative Affiliate Transactions, automatically converted into approximately 87,109 shares of Common Stock, (D) $197,421 and accrued interest of $8,169 as of February 21, 2024 outstanding under our senior secured convertible notes issued in the September Bridge Financing (as defined below) after giving effect to the Representative Affiliate Transactions, automatically converted into approximately 43,385 shares of Common Stock, which includes an additional 549 shares of Common Stock issuable as consideration for the September Bridge Financing (the "Bonus Shares"), (E) we issued 37,500 shares of Common Stock to an investor as consideration for its previous agreement to provide funding that is no longer necessary in connection with the IPO, (F) we effected the Representative Affiliate Transactions, (G) we effected the transactions contemplated by the Holdings Side Letter, and issued an aggregate of 2,600 shares of Series C Preferred Stock to Chromocell Holdings pursuant thereto, and (H) we issued (i) 93,823 shares to a lender holding the Investor Note and (ii) 29,167 shares to one of our directors holding the promissory note in the aggregate principal amount of $175,000 (the "Director Note") in full satisfaction of our obligations thereunder (in the case of (A) through (D) and (H) above, based on the IPO price of $6.00 per IPO Share). We refer to these actions as the "IPO Transactions." In this Report, we include certain metrics on an "as adjusted" basis to give effect to the IPO Transactions.

In addition, certain Selling Stockholders, as identified in the Registration Statement, have agreed to offer for resale of up to an aggregate of 2,969,823 Selling Stockholder Shares to the public. After conversion of the convertible notes or shares of preferred stock, as applicable, the Selling Stockholders, or their respective transferees, pledgees, donees or other successors-in-interest, may sell the Selling Stockholders Shares through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. We will not receive any proceeds from the sale of the Selling Stockholder Shares by the Selling Stockholders.

Trends and Other Factors Affecting Our Business

On December 23, 2023, we entered into the Benuvia License Agreement for the Spray Formulations, diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The Diclofenac Spray Formulation is patented and has started clinical development in human volunteers. Preliminary pharmacokinetics suggest that this formulation may have a faster onset of action than oral Diclofenac tablets. Diclofenac is an NSAID that is also marketed under additional brand names including Voltaren and Cataflam in its pill form. Rizatriptan, whose brand name is Maxalt, is used for the acute treatment of Migraines as a pill. By a number of clinical measures it is thought to be superior to Sumatriptan. A sublingual formulation of Rizatriptan may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea as a result of the migraine headache. Ondansetron is an anti-emetic that is available in oral and intravenous form. An Ondansetron sublingual spray formulation may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations.

In connection with the Benuvia License Agreement, we agreed to pay Benuvia a six and one-half percent (6.5%) royalty on net sales of the Spray Formulations for a period of up to 15 years from the date of the first commercial sale of any of the Spray Formulations. In addition, on December 23, 2023, we entered into a stock issuance agreement with Benuvia (the "Benuvia Stock Issuance Agreement") pursuant to which we issued to Benuvia 384,226 shares of our Common Stock, which may be offered and sold pursuant to the Resale Prospectus.

While we currently do not have strategy and development plans for the Spray Formulations licensed from Benuvia, beginning in the third quarter of 2024, we plan to develop clinical programs for each of the Spray Formulations, determine the labelling strategy that would be obtained from completion of these programs and discuss with the FDA the requirements for bringing each of the Spray Formulations to market. We anticipate bringing the Spray Formulations to market through the FDA 505(b)(2) regulatory pathway for new drug applications; however, the exact details will require further consultation with the FDA.

As a result, our results of operations and balance sheets may not be indicative of future operating results or of our future financial condition.

Going Concern

For the years ended December 31, 2023 and 2022, we had a net loss of $7.4 million and $2.5 million, respectively, and will require significant additional capital in order to operate in the normal course of business and fund clinical studies. The IPO closed on February 21, 2024. The Company received net proceeds from the IPO of approximately $5.7 million after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company (excluding any exercise of the warrants issued to the Representative or its designees, in connection with the IPO).

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022:

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022	$ Change	% Change
OPERATING EXPENSES				
General and administrative expenses	$ 2,738,948	$ 1,098,848	$ 1,640,100	149%
Research and development	2,579,418	391,730	2,187,688	558%
Professional fees	1,543,918	827,581	716,337	87%
Total operating expenses	6,862,284	2,318,159	4,544,125	196%
Loss from operations	(6,862,284)	(2,318,159)	(4,544,125)	(196)%
Other expense	(518,509)	(140,430)	(378,079)	269%
Net loss before provision for income taxes	(7,380,793)	(2,458,859)	(4,922,204)	200%
Provision for income taxes	—	—	—	NA
Net loss	$ (7,380,793)	$ (2,458,589)	$ (4,922,204)	200%

Operating Expenses

Our operating expenses consist of general and administrative expenses, research and development expenses and professional fees.

General and Administrative Expenses

We incurred general and administrative expenses for the years ended December 31, 2023 and 2022 of $2,738,948 and $1,098,848, respectively. For the year ended December 31, 2023, compared to the same period in 2022, this represented an increase of $1,640,100, or 149%, primarily as a result of increases of $1,623,087 in stock-based compensation.

Research and Development Expenses

We incurred research and development expenses for the years ended December 31, 2023 and 2022 of $2,579,418, and $391,730, respectively. For the year ended December 31, 2023, compared to the same period in 2022, this represented an increase of $2,187,688, or 558%, with the details set forth in the table below:

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022	$ Change	% Change
Consultant	$ 68,900	$ 86,802	$ (17,902)	(21)%
Lab Gas	—	13,871	(13,871)	(100)%
Lab Cell Storage	48,572	62,197	(13,625)	(22)%
Chemistry Manufacturing and Controls (“CMC”)	—	3,800	(3,800)	(100)%
IP Services	2,461,946	225,060	2,236,886	994%
Total	$ 2,579,418	$ 391,730	$ 2,187,688	558%

The Company incurred higher research and development expenses for the years ended December 31, 2023, versus the corresponding period in 2022 primarily as a result of intellectual property services and licensing fees in support of the patent portfolio and development of CC8464. A total of $2.2 million in IP service expenses was recognized from the issuance of 384,226 shares of the Company’s Common Stock in connection with the Benuvia License Agreement.

Professional Fees

We incurred professional expenses for the years ended December 31, 2023 and 2022 of $1,543,918 and $827,581, respectively. For the year ended December 31, 2023, compared to the same period in 2022, this represented an increase of $716,337, or 196%, as a result of higher auditing and legal expenses associated with IPO readiness activities.

Other (Expense) Income

We incurred other expense for the year ended December 31, 2023 of $518,509 as compared to other expense for the year ended December 31, 2022 of $140,430. For the year ended December 31, 2023, compared to the same period in 2022, this represented an increase of $378,079 or 269%. The other expense for the years ended December 31, 2023 and 2022 was the result of interest expense. The increase in the interest expense was due to an increase in notes payable and shares issued for the extension of existing debt as of December 31, 2023 when compared to December 31, 2022.

Liquidity

Sources of Liquidity and Capital

We are in our early stages of development and growth, without established records of sales or earnings. We will be subject to numerous risks inherent in the business and operations of financially unstable and early stage or emerging growth companies. We have not yet commercialized any products, and we do not expect to generate revenue from product sales of any of our compounds for several years.

Cash totaled $0.1 million and $0.1 million as of December 31, 2023 and December 31, 2022, respectively. As of December 31, 2023 and December 31, 2022, we had an accumulated deficit of approximately $13.5 million and $6.1 million, respectively, and had a working capital deficit of $6.4 million and $3.7 million, respectively.

Historically, we have funded our operations from a series of cash advances from Chromocell Holdings, licensing arrangements, bridge and note issuances and grants from the National Institutes of Health.

Starting in May 2021, we received a series of advances from Chromocell Holdings that were subsequently codified in the Contribution Agreement as an equity investment, pursuant to which, the Company issued 1,111,112 shares of Common Stock and 600,000 shares of Series A Preferred Stock to Chromocell Holdings in exchange for the assets contributed by Chromocell Holdings to the Company.

On February 4, 2022, the Company entered into the Investor Note, as amended from time to time, for $450,000. The Investor Note has an original issuance discount of $150,000, a maturity date of February 3, 2023, and accrues no interest. As of September 30, 2023, the debt discount was fully amortized. On February 27, 2023, the maturity date of the Investor Note was extended to May 15, 2023, in return for the payment of monthly interest of 2% on the full value, which shall accrue, and the Holder of the Investor Note agreeing to settle the Investor Note in IPO Shares. On June 23, 2023, we entered into a side letter with the Holder of the Investor Note (the "June Investor Note Side Letter"), pursuant to which the Investor Note was further amended to extend the maturity date to August 15, 2023 and we issued to the Holder 5,556 shares of Common Stock. On August 17, 2023, we entered into a side letter with the Holder of the Investor Note (the "August Investor Note Side Letter"), which extended the maturity date to September 30, 2023 and we issued to the Holder of the Investor Note 3,334 shares of Common Stock. On September 24, 2023, we entered into an amendment to the Investor Note, which extended the maturity date to October 10, 2023. Effective October 10, 2023, we entered into a side letter with the Holder of the Investor Note (the "October Investor Note Side Letter"), which extended the maturity date to November 14, 2023, and we issued to the Holder of the Investor Note 3,334 shares of Common Stock. Effective November 13, 2023, we entered into the November Investor Note Side Letter, which further extended the maturity date to January 31, 2024, and we agreed to issue to the Holder of the Investor Note 3,334 shares of Common Stock on each of November 29, 2023, December 29, 2023 and January 29, 2024, provided the Investor Note remained outstanding as of such date. Effective January 30, 2024, we entered into the January Investor Note Side Letter, which further extended the maturity date to February 29, 2024, and we agreed to issue to the Holder of the Investor Note 77,778 shares of Common Stock on the earlier to occur of the IPO or February 29, 2024.

On December 6, 2022, the Company and Mr. Todd Davis, one of our directors, entered into the Director Note for $175,000. The Director Note has an original issuance discount of $75,000, and matures on December 31, 2023, or, if earlier to occur, upon the closing of an underwritten offering of securities resulting in at least $15 million in gross proceeds. Mr. Davis, as lender, has the right but not the obligation to subscribe to the underwritten offering by presenting the Director Note in whole or in part to purchase such securities as legal tender therefor, on a dollar-for-dollar basis based upon the offering price of such securities to the public. The Director Note bears no interest except in the case of certain events of default. As of December 31, 2023, there was an unamortized debt discount of $0. On December 28, 2023, we entered into an amendment to the Director Note, which extended the maturity date to February 29, 2024.

On April 17, 2023, we entered into a bridge loan for working capital purposes, with various accredited investors, all of whom are pre-existing stockholders, in the aggregate principal amount of $389,757 (the "April Bridge Financing", and together with the September Bridge Financing, the "Bridge Financings"), after giving effect to the Representative Affiliate Transactions. During the nine months ended September 30, 2023, the Company received advances in the amount of $166,903 (the "Advances") prior to the close of the April Bridge Financing from certain of the participating investors. Such Advances accrued interest at a rate of eight percent (8%) per annum until close of the April Bridge Financing on April 17, 2023, for a total of $1,870 in aggregate interest on all Advances. The April Bridge Financing consists of senior secured convertible notes that had a maturity date of October 17, 2023. On October 12, 2023, we entered into a first amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 1, 2023. On October 24, 2023, we entered into a second amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 14, 2023. On November 13, 2023, we entered into a third amendment to the senior secured convertible notes in the April Bridge Financing, which further extended the maturity of the notes to February 29, 2024. Such notes accrue interest on the unpaid principal amount at a rate of eight percent (8%) per annum and will automatically convert into 87,109 shares of Common Stock in connection with the IPO at a twenty percent (20%) discount to the price per IPO Share (based on the IPO price of $6.00 per IPO Share). The senior secured convertible notes issued in the April Bridge Financing are secured by a security interest in all of our assets (including our patents and intellectual property licenses). In connection with the April Bridge Financing, on April 17, 2023, we also entered into a securities purchase agreement with holders of the notes, pursuant to which we are required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock received by holders of the notes upon conversion of such notes.

On August 2, 2023, we entered into the Holdings Side Letter to the Contribution Agreement. Pursuant to the Holdings Side Letter, upon closing of the IPO: (a) Chromocell Holdings re-assumed all $1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings waived the Company's obligations to make a cash payment in the amount of $0.6 million to Chromocell Holdings, and (c) in consideration thereof, we issued to Chromocell Holdings 2,600 shares of Series C Preferred Stock.

The Series C Preferred Stock has a liquidation preference of $1,000 per share. Holders of the Series C Preferred Stock are not entitled to dividends, have no voting rights other than as required by law, are convertible into shares of Common Stock at the holder's option, convert into shares of Common Stock automatically if the trading price of the Common Stock exceeds certain thresholds, and are redeemable by the Company for cash. For more information, see "Description of Capital Stock–Series C Preferred Stock."

On September 1, 2023, we entered into a bridge loan for working capital purposes, with various accredited investors, all of whom are pre-existing stockholders, in the aggregate principal amount of $197,421 (the "September Bridge Financing"), after giving effect to the Representative Affiliate Transactions. The September Bridge Financing consists of senior secured convertible notes that have a maturity date of March 1, 2024. Such notes accrue interest on the unpaid principal amount at a rate of eight percent (8%) per annum and automatically converted into shares of Common Stock in connection with the IPO at a twenty percent (20%) discount to the price per IPO Share plus 549 Bonus Shares (43,385 shares, based on the IPO price of $6.00 per IPO Share). The senior secured convertible notes issued in the September Bridge Financing are secured by a security interest in all of our assets (including our patents and intellectual property licenses). In connection with the September Bridge Financing, on September 1, 2023, we also entered into a securities purchase agreement with holders of the notes, pursuant to which we are required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock received by holders of the notes upon conversion of such notes. Additionally, we entered into a subordination and intercreditor agreement, effective September 1, 2023, with the holders of the senior secured convertible notes issued in the April Bridge Financing, pursuant to which those notes and certain liens of the Company will be subordinated to the rights of the holders of the notes issued in the September Bridge Financing.

In connection with the September Bridge Financing, the Company and certain holders of the senior secured convertible notes issued in the April Bridge Financing and the September Bridge Financing agreed to waive certain prohibitions in order to permit the issuance of Series C Preferred Stock and the shares of Common Stock issuable in connection with the IPO.

On October 11, 2023, we entered into a securities purchase agreement with an institutional investor (the "Standby Investor") pursuant to which (i) the Standby Investor agreed to purchase, upon close of the IPO and at our election, an aggregate of up to 750 shares of Series B Convertible Preferred Stock, par value of $0.0001 per share (the "Series B Preferred Stock") for a purchase price of $1,000 per share, and (ii) in consideration therefor, we would issue upon close of the IPO, and regardless of whether we would have issued any shares of Series B Preferred Stock, an aggregate of 37,500 shares of Common Stock (such shares, the "Standby Shares") to the Standby Investor. In addition, pursuant to the Series B Securities Purchase Agreement, we were required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of the Standby Shares and shares of Common Stock issuable upon conversion of the Series B Preferred Stock, if issued. Effective November 13, 2023, we entered into a side letter with the Standby Investor (the "Standby Investor Side Letter"), pursuant to which we (i) waived in full the Standby Investor's obligation to fund the aggregate amount to be paid for the Series B Preferred Stock to be purchased under the Series B Securities Purchase Agreement and (ii) agreed to continue to have the obligation to issue the full amount of the Standby Shares upon the closing of the IPO. We and the Standby Investor also agreed to terminate each of our obligations solely with respect to the Series B Preferred Stock under the Series B Securities Purchase Agreement and that certain Registration Rights Agreement between us and the Standby Investor, which was required to be delivered pursuant to the Series B Securities Purchase Agreement.

On October 12, 2023, we and four existing investors entered into promissory notes (the "October Promissory Notes") with an aggregate face amount of $210,000 and an aggregate purchase price of $175,000. The October Promissory Notes mature on November 12, 2023 or, if earlier to occur, upon the closing of the IPO. The October Promissory Notes bear no interest except in the case of certain events of default. On November 7, 2023, we amended and restated the October Promissory Notes to extend the maturity dates of the October Promissory Notes to November 17, 2023. On November 13, 2023, we amended and restated the October Promissory Notes to further extend the maturity dates of the Promissory Notes to February 29, 2024.

On November 22, 2023, we commenced a rights offering (the "Rights Offering") pursuant to which we distributed non-transferable subscription rights ("Subscription Rights") to each holder of our Common Stock held as of 5:00 p.m. Eastern Standard Time on November 22, 2023, the record date for the Rights Offering (the "Rights Offering Record Date"). The Subscription Rights could be exercised at any time during the subscription period, which commenced on November 22, 2023 and expired at 5:00 p.m., Eastern Standard Time, on December 1, 2023. Each Subscription Right entitled the eligible holder to purchase up to three shares of our Common Stock at a price per whole share of Common Stock of $0.1008 (the "Subscription Price"). Holders who fully exercised their rights could also subscribe for additional shares of Common Stock not subscribed for by other holders on a pro rata basis. In addition, we could distribute to one or more additional persons, at no charge to such person, additional non-transferable subscription rights to purchase shares of our Common Stock in the Rights Offering at the same Subscription Price, without notice to the holders of our Common Stock. Upon the closing of the Rights Offering, we issued an aggregate of 2,442,469 shares of our Common Stock and received aggregate net proceeds of $246,201, after giving effect to the Representative Affiliate Transactions, which we intend to use primarily for general corporate purposes and expenses associated with our IPO.

We are negotiating an arrangement with the Holder of the Investor Note to enter into an ELOC subsequent to the IPO, pursuant to which we will have the right, but not the obligation, to sell to the Holder of the Investor Note up to $20,000,000 in newly issued shares of our Common Stock, subject to certain limitations. Pursuant to the terms of the proposed arrangement, we will pay the holder a commitment fee of $1,000,000, which may be paid at our election, in cash or shares of Common Stock, upon entry into the ELOC. In addition, we will agree to certain registration rights pursuant to which we will register the securities issuable under the ELOC subsequent to the expiration of the lock-up agreement we enter into with the Representative in connection with the IPO. We also intend to agree, during the proposed two-year term of the ELOC, to not enter into any variable, reset, or otherwise adjustable equity or equity-linked transactions. In the event we do not close the ELOC within forty-five (45) days of the consummation of the IPO and have the registration statement referred to above effective within ninety (90) days of the expiration of any IPO standstill period, we expect to be obligated to pay to the holder a break-up fee in the amount of $1,000,000 and will not be able to raise capital for sixty (60) days thereafter; provided that, we and the Holder of the Investor Note may agree to enter into other form of investments, such as a private investment in public equity transaction.

We anticipate that we will enter into a purchase agreement to issue the shares of Common Stock issuable pursuant to the ELOC; however, as of the date hereof, an agreement with respect to our proposed ELOC has not been, and may never be, finalized and executed and there is no assurance that we will enter into an ELOC or, if we do enter into such an ELOC, that the terms thereof will be consistent with or as favorable as those described in this Report.

On February 8, 2024, we and certain affiliates of the Representative entered into amendments to the senior secured convertible notes issued to such affiliates of the Representative in the April Bridge Financing and September Bridge Financing to remove the automatic conversion features from such notes (the "Bridge Financing Note Amendments"). Under the Bridge Financing Note Amendments, both notes issued in the April Bridge Financing and the September Bridge Financing had a maturity date of March 1, 2024, and the full principal amount of both notes and any accrued interest thereon was payable solely in cash upon the consummation of the IPO. Both notes had an annual interest rate of eight percent (8%), which accrued daily, and was calculated on the basis of a 360-day year (consisting of twelve 30 calendar day periods).

On February 10, 2024, we entered into a Stock Rescission Agreement with certain affiliates of the Representative (the "Stock Rescission Agreement" and, together with the Bridge Financing Note Amendments, the "Representative Affiliate Transactions"), pursuant to which we rescinded 111,129 shares of our Common Stock held by such affiliates of the Representative and agreed to refund an aggregate of $91,512.53 paid by such affiliates of the Representative in consideration therefor within 30 days of the effective date of the Stock Rescission Agreement.

On February 21, 2024, we completed the IPO and issued and sold 1,100,000 shares of Common Stock at a price to the public of $6.00 per share. The aggregate net proceeds from the IPO were approximately $5.7 million after deducting underwriting discounts and commissions and offering expenses.

In connection with the completion of the IPO: (A) we have effected a 1-for-9 Reverse Stock Split, (B) all 600,000 issued and outstanding shares of our Series A Preferred Stock automatically converted into 499,429 shares of Common Stock, (C) $389,757 and accrued interest of approximately $28,336 as of February 21, 2024 outstanding under our senior secured convertible notes issued in the April Bridge Financing after giving effect to the Representative Affiliate Transactions, automatically converted into approximately 87,109 shares of Common Stock, (D) $197,421 and accrued interest of $8,169 as of February 21, 2024 outstanding under our senior secured convertible notes issued in the September Bridge Financing after giving effect to the Representative Affiliate Transactions, automatically converted into approximately 43,385 shares of Common Stock, which includes an additional 549 Bonus Shares issuable as consideration for the September Bridge Financing, (E) we issued 37,500 shares of Common Stock to an investor as consideration for its previous agreement to provide funding that is no longer necessary in connection with the IPO, (F) we effected the Representative Affiliate Transactions, (G) we effected the transactions contemplated by the Holdings Side Letter, and issued an aggregate of 2,600 shares of Series C Preferred Stock to Chromocell Holdings pursuant thereto, and (H) we issued (i) 93,823 shares to a lender holding the Investor Note and (ii) 29,167 shares to one of our directors holding the Director Note in full satisfaction of our obligations thereunder (in the case of (A) through (D) and (H) above, based on the IPO price of $6.00 per IPO Share). In this Report, we include certain metrics on an "as adjusted" basis to give effect to the IPO Transactions.

In addition, certain Selling Stockholders, as identified in the Registration Statement, have agreed to offer for resale of up to an aggregate of 2,969,823 Selling Stockholder Shares to the public. After conversion of the convertible notes or shares of preferred stock, as applicable, the Selling Stockholders, or their respective transferees, pledgees, donees or other successors-in-interest, may sell the Selling Stockholders Shares through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. We will not receive any proceeds from the sale of the Stockholder Shares by the Selling Stockholders.

Future Funding Requirements

Our primary use of cash is to fund clinical development, operating expenses and repay accrued liabilities associated with our IPO.

With respect to the Company's future expected operations expenses, the primary expense drivers will be research and development and management overhead, including costs of being a public company. Of these, it is expected that research and development will be the largest expense and comprise approximately $3.0 million in the twelve months following the IPO, which will be utilized for the Company's escalation study and Phase II drug trial costs. We have based the research and development costs on current trial parameters and expectations on certain existing tax credits, and there is no certainty that the trial parameters or tax credits available to the Company will remain as they are, which could lead to changes in our research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

We expect to continue to incur significant and increasing expenses and operating losses in connection with our ongoing research and development activities. In addition, upon the closing of the IPO, we expect to incur additional costs associated with operating as a public company. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Based on our current operating plan, we believe that the net proceeds from the IPO, together with our existing cash, will be sufficient to fund our operations and capital expenses through the end of 2024. However, we have based this estimate on assumptions that may prove to be incorrect, and we could exhaust our capital resources sooner than we expect.

We may also raise additional funding through strategic relationships, public or private equity or debt financings, credit facilities, grants or other arrangements. If such funding is not available or not available on terms acceptable to us, our current development plan and plans for expansion of our general and administrative infrastructure may be curtailed. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that restrict our operations. Any other third- party funding arrangement could require us to relinquish valuable rights.

The source, timing and availability of any future financing will depend principally upon market conditions. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us to, among other things, delay, scale back or eliminate expenses including some or all of our planned development. There is substantial doubt about our ability to continue as a going concern.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2023 and 2022:

	For the Twelve Months Ended December 31, 2023	For the Twelve Months Ended December 31, 2022	$ Change	% Change
Net cash used in operating activities	$ (981,031)	$ (1,567,149)	$ 586,118	(37)%
Net cash used in investing activities	—	—	—	—
Net cash provided by financing activities	1,022,348	1,622,223	(599,875)	(37)%
Net increase in cash	$ 41,317	$ 55,074	$ (13,757)	(25)%

Net Cash Used in Operating Activities

For the year ended December 31, 2023, we incurred a net loss of $7,380,793, and net cash flows used in operating activities was $981,031. The cash flow used in operating activities was primarily due to a net loss of $7,380,793, offset by stock-based compensation expense of $1,733,233, shares issued for license of $2,225,733, a change in account payable and accrued expense of $1,627,005, share issuance cost associated with the extension of the bridge loan in the amount of $201,600 and an increase in accrued compensation in the amount of $424,072.

For the year ended December 31, 2022, we incurred a net loss of $2,458,589, and net cash flows used in operating activities was $1,567,149. The cash flow used in operating activities resulted from the net loss of $2,458,589, primarily offset by $110,146 in stock-based compensation expenses, $140,430 of debt discount amortization, an increase in accounts payable and accrued expenses of $413,603 and an increase in accrued compensation of $221,875.

Net Cash (Used in) Provided by Investing Activities

The Company neither received nor used cash in investing activities during the years ended December 31, 2023 and 2022.

Net Cash Provided by Financing Activities

For the year ended December 31, 2023, net cash flows provided by financing activities were $1,022,348 resulting from proceeds from loans of $766,936, with $565,928 of that amount derived from related parties and $255,412 from share issued for cash.

For the year ended December 31, 2022, net cash flows provided by financing activities were $1,622,223, consisting of cash received from an advance by Chromocell Holdings in the amount of $800,050, cash transfers from Chromocell Holdings to the Company in the amount of $422,173 and total net proceeds from the issuance of two notes in the amount of $400,000.

Off-Balance Sheet Arrangements

During the years ended December 31, 2023 and 2022, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Critical Accounting Estimates

The following discussions are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States.

The preparation of these financial statements requires management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingencies. We continually evaluate the accounting policies and estimates used to prepare the financial statements. We base our estimates on historical experiences and assumptions believed to be reasonable under current facts and circumstances. Actual amounts and results could differ from these estimates made by management.

See Note 3 – Summary of Significant Accounting Policies to the accompanying financial statements for a detailed description of our significant accounting policies.

Income Taxes

We are subject to income taxes in the U.S. Significant judgment is required in determining income tax expense, deferred taxes and uncertain tax positions. The underlying assumptions are also highly susceptible to change from period to period. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some or all the deferred tax assets will be realized. The ultimate realization of deferred taxes assets is dependent upon generation of future taxable income during the period in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and taxable income in carryback years and tax-planning strategies when making this assessment. There is currently significant negative evidence which contributes to our recording a valuation allowance against our deferred tax assets due to cumulative losses since inception.

Although we believe our assumptions, judgments, and estimates are reasonable, changes in tax laws or our interpretation of tax laws and the resolution of any tax audits could significantly impact the amounts provided for income taxes in our consolidated financial statements. The effect on deferred tax assets and liabilities from a change in tax rates is recognized in income in the period that includes the enactment date. Adjustments to income tax expense, to the extent we establish a valuation allowance or adjust the allowance in a future period, could have a material impact on our financial condition and results of operations.

The critical accounting estimates below do not represent a material estimate in the preparation of our financial statements.

Recently Issued and Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update, or ASU, No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, or ASU 2019-12, which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The adoption of ASU 2019-12 did not have a material effect on the Company’s financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments (ASU 2016-13), which requires an entity to utilize a new impairment model known as the current expected credit loss (CECL) model to estimate its lifetime “expected credit loss” and record an allowance that, when deducted from the amortized cost basis of the financial assets and certain other instruments. ASU 2016-13 requires a cumulative effect adjustment to the balance sheet as of the beginning of the first reporting period in which the guidance is effective. In November 2019, the FASB issued ASU 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates, which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022 for all entities except SEC reporting companies that are not smaller reporting companies. ASU 2016-13 became effective for the Company beginning January 1, 2023. The adoption of this ASU did not have a material effect on the Company’s financial statements.

In August 2020, the FASB issued ASU 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 740-20) and Derivates Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40), which simplifies the guidance on the issuer’s accounting for convertible debt instruments by removing the separation models for convertible debt with a cash conversion feature and convertible instruments with a beneficial conversion feature. As a result, entities will not separately present in equity an embedded conversion feature in such debt and will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. The elimination of these models will reduce reported interest expense and increase reported net income for entities that have issued a convertible instrument that is within the scope of ASU 2020-06. Also, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and treasury stock method will be no longer available. ASU 2020-06 is applicable for fiscal years beginning after December 15, 2022, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The adoption of this ASU did not have a material effect on the Company’s financial statements.

The FASB issues ASUs to amend the authoritative literature in the Accounting Standards Codification ("ASC"). There have been several ASUs to date, including those above, that amend the original text of ASC. Management believes that those issued to date either (i) provide supplemental guidance, (ii) are technical corrections, (iii) are not applicable to us or (iv) are not expected to have a significant impact on our financial statements.

Other accounting standards that have been issued or proposed by FASB and do not require adoption until a future date are not expected to have a material impact on the consolidated financial statements upon adoption. Management does not believe that any other recently issued, but not yet effective, accounting standard if currently adopted would have a material effect on the accompanying financial statements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

We are not required to provide the information required by this Item 7A as we are a smaller reporting company.

Item 8. Financial Statements and Supplementary Data.

The Company's financial statements, notes to the financial statements, and the reports of the Company's independent registered accountants required to be filed in response to this Item 8 begin on page F-1 of this Report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15 under the Exchange Act, we have carried out an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Report. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our company's reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective.

Management identified the following material weaknesses:

1. We lack the necessary corporate accounting resources to maintain adequate segregation of duties. Such a lack of segregation of duties is typical in a company with limited resources.

2. We lack the ability to provide multiple levels of review in connection with the financial reporting process, which means that we cannot ensure that we are meeting certain financial reporting and transaction processing controls standards.

3. We lack the necessary internal IT infrastructure to ensure proper IT general controls. Additionally, we are reliant on third-party software for our financial systems and cannot ensure there are no vulnerabilities in these systems.

With the completion of the IPO, the Company is instituting controls and procedures that we expect will demonstrably improve the effectiveness of the Company's disclosure controls and procedures.

Management's Report on Internal Control over Financial Reporting

This Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies. Additionally, our auditors will not be required to formally opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the JOBS Act.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting during the year ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information

During the three months ended December 31, 2023, none of our directors and officers adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement", as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The following table provides information regarding our current executive officers and directors:

Name	Age	Position
Executive Officers		
Francis Knuettel II	57	Chief Executive Officer, Chief Financial Officer, Treasurer and Secretary
Eric Lang	62	Chief Medical Officer
Directors		
Todd Davis	62	Director (Chairman of the Board)
Ezra Friedberg	53	Director
Richard Malamut	64	Director
Chia-Lin Simmons	50	Director

Biographic Information - Executive Officers

Francis Knuettel II has served as our Interim Chief Executive Officer since July 2023, as our Chief Financial Officer, Treasurer and Secretary since June 2022 and as our Chief Executive Officer since March 2024. Prior to that, from December 2020 to April 2022, he served as Chief Executive Officer and director of Unrivaled Brands, a California-based operator of cannabis assets in California and Oregon, where he helped grow revenue from an annualized rate of $10 million to $100 million in six quarters by acquiring three companies in the sector. He also served as Chief Financial Officer of ONE Cannabis Group from June 2019 to January 2021 and held various roles at MJardin Group, including Chief Strategy Officer, from August 2018 to January 2019. Prior to MJardin Group, Mr. Knuettel served as Chief Financial Officer of Aqua Metals in 2018 and held the same position at Marathon Patent Group from 2014 to 2018. During Mr. Knuettel's career, he has helped raise more than $300 million via venture equity and debt, public equity and debt offerings in the United States and Canada, convertible debt, PIPEs, bridge loans and other instruments. In addition, he has managed more than 15 mergers and acquisition transactions of companies as both buyer and seller and has handled large-scale licensing transactions with fortune 50 companies. Mr. Knuettel also holds numerous board positions at both public and private companies, including ECOM Medical since 2019, Relativity Acquisition Corp. (Nasdaq: RACY) since 2022, and Capstone Technologies Group Inc (OTC: CATG) since 2023. Mr. Knuettel received his BA with honors in Economics from Tufts University and holds an MBA in Finance and Entrepreneurial Management from The Wharton School at the University of Pennsylvania.

Eric Lang has served as our Chief Medical Officer since June 2023. Prior to that, from September 2018 to May 2023, Dr. Lang served at Nevakar Inc, initially as Vice President of Clinical Development and later as its Chief Medical Officer. From January 2018 to September 2018, Dr. Lang served as the Chief Medical Officer at Entera Bio Ltd. (Nasdaq: ENTX). From February 2012 to November 2017, he served at Covance (now Labcorp Drug Development), heading an international team that assisted smaller biotech companies in moving their programs through the various phases of pre-clinical and clinical development. From August 2010 to January 2012, Dr. Lang served at Grunenthal USA, Inc. as their head of clinical development. Prior to that, Dr. Lang led the clinical development team at Javelin Pharmaceuticals, Inc. from October 2008 to August 2010, which was acquired by Hospira (now Pfizer Inc.) in 2010. Dr. Lang worked for Novartis Consumer Health from October 2006 to October 2008 and he began his career with Johnson & Johnson (NYSE: JNJ) where he worked from 1999 to 2006. Dr. Lang is an Anesthesiologist and Pain Management Specialist with over 26 years of experience in the pharmaceutical industry. During his pharmaceutical career, he has had both broad-based drug and device development expertise in a variety of therapeutic areas. Dr. Lang has experience in designing development programs from early translational stages through phase III including the successful filing of several recent INDs and NDAs. He has experience with regulatory interactions and negotiations with FDA and various European and Asian Authorities. Dr. Lang received his Doctor of Medicine from Ben-Gurion University of the Negev and completed post graduate training at Emory University in Atlanta, GA.

Biographical Information - Directors

Todd Davis has served as a member of our board of directors since January 2023. He is the founder and has served as the managing partner of RoyaltyRx Capital, LLC, a special opportunities investment firm, since 2018. Since November 2019, he has also served as Chairman and CEO of Benuvia Holdings, LLC, a pharmaceutical holding company. From 2006 to 2018, Mr. Davis was a founder and managing partner of Cowen/HealthCare Royalty Partners, a global healthcare investment firm. From 2004 to 2006, Mr. Davis was a partner at Paul Capital Partners, where he co-managed its royalty investments as a member of the Royalty Management Committee. From 2001 to 2004, he served as a partner responsible for biopharmaceutical growth equity investments at Apax Partners. Mr. Davis began his business career in sales at Abbott Laboratories where he held several commercial roles of increasing responsibility. He subsequently held general management, business development, and licensing roles at Elan Pharmaceuticals. Mr. Davis is a navy veteran and received a B.S. from the U.S. Naval Academy and an M.B.A. from the Harvard Business School. He currently serves on the board of directors of Palvella Therapeutics Inc., BioDelivery Sciences International, Inc., and Ligand Pharmaceuticals Incorporated. He is also a board member of the Harvard Business School Healthcare Alumni Association. We believe Mr. Davis is qualified to serve on the board of directors because of his extensive experience within the life sciences industry, including as a founder and managing partner of a special opportunities investment firm.

Ezra Friedberg has served as a member of our board of directors since May 2021. Since September 2011, Mr. Friedberg has served as co-founder and general partner of Multiplier Capital, a fund focused on lending opportunities to sponsor-backed growth companies. He is also a member of the fund's credit committee. Mr. Friedberg is a seasoned investor with more than twenty years of investing experience in both public and private companies. He invests actively in the biotech space and has served on the board of directors of Humanigen (Nasdaq: HGEN), a clinical-stage biopharmaceutical company which develops monoclonal antibodies. His other investments include private equity, venture capital, and property across the United States, Canada and overseas. Separately, Mr. Friedberg manages and owns other investments and businesses through Liberty Peak Capital, Key Recovery Group, and related companies. Mr. Friedberg is a graduate of Johns Hopkins University. He has founded and is an active board member of several community and civic organizations, including a non-profit mentoring agency. Mr. Friedberg serves and has served on several for-profit and non-profit boards. He was selected to serve on our board of directors due to his investment experience and his knowledge of our industry.

Dr. Richard Malamut has served as a member of our board of directors since January 2023. Dr. Malamut is currently Chief Medical Officer at MedinCell Inc. He was most recently Chief Medical Officer and Executive Vice President at Collegium Pharmaceuticals from April 2019 to May 2022 and has also served as Chief Medical Officer for Braeburn Pharmaceuticals, Inc. from 2018 to 2019 where he was responsible for the company's medical affairs, non-clinical and clinical development, clinical operations, research and development quality assurance, and pharmacovigilance functions. Prior to that, Dr. Malamut had similar responsibilities as Chief Medical Officer at Avanir Pharmaceuticals from 2016 to 2018 and was Senior Vice President of Global Clinical Development at Teva Pharmaceutical Industries Ltd from 2013 to 2016 where he was responsible for Pain, Neuropsychiatry, Oncology, and New Therapeutic Entities. His experience also includes roles of increasing responsibility focusing on early clinical development and translational medicine in Neurology, Psychiatry and Analgesia at Bristol-Myers Squibb and AstraZeneca. Dr. Malamut earned his medical degree from Hahnemann University in Philadelphia and completed both a residency in Neurology and a fellowship in Neuromuscular disease. He worked as a board-certified academic and clinical neurologist for 17 years and has more than 50 publications in the fields of pain medicine, neuromuscular disease, autonomic disease, and neurodegenerative disease. He was selected to serve on our board of directors due to his experience and knowledge of our industry.

Chia-Lin Simmons has served as a member of our board of directors since March 2023. Since June 2021, Ms. Simmons has served as Chief Executive Officer and as a director of LogicMark, Inc. (Nasdaq: LGMK), a company that develops medical alert devices and related technologies. Ms. Simmons currently also serves as a member of the board of directors for Servco Pacific Inc., a global automotive and consumer goods company with businesses in mobility, automotive distribution and sales, and entertainment, and for New Energy Nexus, an international organization that supports clean energy entrepreneurs with funds, accelerators, and networks. From 2016 to June 2021, Ms. Simmons served as the Chief Executive Officer and co-founder of LookyLoo, Inc., an artificial intelligence social commerce company. From 2014 to 2016, Ms. Simmons served as Head of Global Partner Marketing at Google Play, prior to which, between 2010 and 2014, she served as VP of Marketing & Content for Harman International. Ms. Simmons received her B.A. in Communications, Magna cum Laude, and Phi Beta Kappa, from the University of California, San Diego in 1995. She also received her M.B.A. from Cornell University in 2002, where she was a Park Leadership Fellow, and her J.D. from George Mason University in 2005, and is currently a licensed attorney in the State of New York. She was selected to serve on our board of directors due to her experience serving on the boards of directors of public companies.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Involvement in Certain Legal Proceedings

None.

Code of Ethics

We have a written code of conduct and ethics that applies to our directors, officers, employees and contractors, including our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. The code of conduct and ethics is available on our website at *www.chromocell.com*. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions or our directors on our website identified above or in a Current Report on Form 8-K that we would file with the SEC.

Delinquent Section 16(a) Reports

Under the securities laws of the United States, our directors, executive (and certain other) officers, and any persons holding ten percent or more of our Common Stock must report on their ownership of the Common Stock and any changes in that ownership to the SEC. Specific due dates for these reports have been established. During the fiscal year ended December 31, 2023, all reports required to be filed by such persons pursuant to Section 16(a) were filed on a timely basis.

Corporate Governance

Board of Directors

Our board of directors consists of four members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Director Independence

Applicable NYSE American rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, NYSE American rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. The NYSE American independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his family members has engaged in various types of business dealings with us. In addition, under applicable NYSE American rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has determined that all of our non-employee directors, other than Mr. Todd Davis, are independent, as defined under applicable NYSE American rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in the section entitled "Certain Relationships and Related-Party Transactions."

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3 of the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries.

Our executive officers are elected by, and serve at the discretion of, our board of directors.

Board Meetings and Attendance

During the 2023 fiscal year, the board of directors held six (6) board meetings and also conducted other matters by unanimous written consent.

Annual Meeting Attendance

The Company did not hold an annual meeting of its stockholders in the 2023 fiscal year.

Role of our Board of Directors in Risk Oversight

One of the key functions of the board of directors is informed oversight of our risk management process. The board of directors does not anticipate having a standing risk management committee, but rather anticipates administering this oversight function directly through our board of directors as a whole, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has to take to monitor and control such exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our compensation committee also assesses and monitors whether our compensation plans, policies and programs comply with applicable legal and regulatory requirements.

Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and the responsibilities described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee operates under a charter approved by our board of directors. Copies of each committee's charter will be posted on the investor relations section of our website at *www.chromocell.com*.

Audit Committee

Our audit committee is composed of Ezra Friedberg and Chia-Lin Simmons. Ezra Friedberg is the chairperson of our audit committee. The composition of our audit committee meets the requirements for independence under the current NYSE American listing standards and SEC rules and regulations. Each member of our audit committee is financially literate. In addition, our board of directors has determined that Ezra Friedberg is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is responsible for, among other things:

- our accounting and financial reporting processes, including our financial statement audits and the integrity of our financial statements;
- our compliance with legal and regulatory requirements;
- reviewing and approving related person transactions;
- selecting and hiring our registered independent public accounting firm;
- the qualifications, independence and performance of our independent auditors; and
- the preparation of the audit committee report to be included in our annual proxy statement.

Compensation Committee

Our compensation committee is composed of Richard Malamut and Chia-Lin Simmons. Richard Malamut is the chairperson of our compensation committee. The composition of our compensation committee meets the requirements for independence under the current NYSE American listing standards and SEC rules and regulations. Each member of this committee is: (i) an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended; and (ii) a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act. Our compensation committee is responsible for, among other things:

- evaluating, recommending, approving and reviewing executive officer and director compensation arrangements, plans, policies and programs;
- administering our cash-based and equity-based compensation plans; and
- making recommendations to our board of directors regarding any other board of director responsibilities relating to executive compensation.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee is composed of Chia-Lin Simmons and Richard Malamut. Chia-Lin Simmons is the chairperson of our nominating and corporate governance committee. The composition of our nominating and corporate governance committee meets the requirements for independence under the current NYSE American listing standards and SEC rules and regulations. Our nominating and corporate governance committee is responsible for, among other things:

- identifying, considering and recommending candidates for membership on our board of directors;
- overseeing the process of evaluating the performance of our board of directors; and
- advising our board of directors on other corporate governance matters.

Director Nomination Procedures

There have been no material changes to the procedures by which security holders may recommend nominees to our board of directors.

Insider Trading Arrangements and Policies

We have a written insider trading policy that applies to our directors, officers, employees and contractors, including our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. We intend to disclose future amendments to such policy, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions or our directors on our website identified above or in a Current Report on Form 8-K that we would file with the SEC.

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our Common Stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material non-public information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of the pricing of our IPO, subject to early termination, the sale of any shares under such plans would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

Item 11. Executive Compensation.

Our named executive officers for 2023 were Mr. Christian Kopfli, our former Chief Executive Officer and former Chief Strategy Officer, Mr. Francis Knuettel II, our Chief Executive Officer, Chief Financial Officer, Treasurer and Secretary, and Mr. Eric Lang, our Chief Medical Officer. Mr. Knuettel was first appointed in June 2022, and Mr. Lang was first appointed in May 2023.

Summary Compensation Table

The following table provides information regarding the compensation of our named executive officers during the years ended December 31, 2023 and 2022.

Name and Principal Position	Year	Salary	Bonus	Option Awards	Non-Equity Incentive Plan Compensation	All Other Compensation	Total
Christian Kopfli Former Chief Executive Officer, Former Chief Strategy Officer, and Former Vice Chairman [2]	2023	$ 11,280[1]	$ —	$ 2,489	$ —	$ —	$ 13,769
	2022	$ 158,654[1]	$ —	$ 622	$ —	$ —	$ 159,276
Francis Knuettel II Chief Executive and Chief Financial Officer	2023	$ 107,500	$ —	$ 2,489	$ —	$ —	$ 109,989
	2022	$ 30,000	$ —	$ 622	$ —	$ —	$ 30,622
Eric Lang[3] Chief Medical Officer	2023	$ 166,767	$ —	$ 1,507	$ —	$ —	$ 168,274
	2022	$ —	$ —	$ —	$ —	$ —	$ —

[1] Represents the portion of Mr. Kopfli's salary attributable to his services to the Company during the years ended December 31, 2023 and 2022.

[2] Mr. Kopfli stepped down as Chief Financial Officer with the hiring of Mr. Knuettel, effective June 10, 2022. In addition, in July 2023, Mr. Knuettel assumed the role of Interim Chief Executive Officer and stepped down as Chief Strategy Officer, and Mr. Kopfli was appointed Vice Chairman and Chief Strategy Officer. On December 1, 2023, the Company terminated Mr. Kopfli as Vice Chairman and Chief Strategy Officer.

[3] Represents the portion of Mr. Lang's salary attributable to his services to the Company during the year ended December 31, 2023. Mr. Lang was appointed Chief Medical Officer of the Company, effective May 15, 2023.

Employment Agreements and Arrangements

Christian Kopfli

We were a party to an amended and restated employment agreement with Christian Kopfli, dated July 28, 2023. Pursuant to such agreement, Mr. Kopfli agreed to serve as our Vice Chairman and Chief Strategy Officer, in consideration for an annualized salary of $275,000, payable in cash at the rate of $5,000 per month (a minimum of $1,125 per week), with the remainder accrued and paid as of the earliest of a sale or liquidation of the Company, the Company's bankruptcy or three days after the approval by the board of directors of a funded budget with appropriately established milestones subsequent to the effective date of a Form S-1 registration statement ("Post-registration Approval"). Mr. Kopfli also agreed, as of Post-registration Approval, to resign as Chief Executive Officer of Chromocell Corporation although he could continue to serve on the board of directors of Chromocell Corporation, including as its board of directors Chair. The employment agreement provided that Mr. Kopfli receive an option to acquire 200,000 shares of our Common Stock, vesting quarterly over 10 quarters and beginning October 1, 2022. This option shall have an exercise price equal to the fair market value of our Common Stock on the date of grant and shall expire on the 10th anniversary of the date of grant. The option was awarded as of January 10, 2023. The employment agreement contemplated an annual bonus, as determined by the board of directors. The target bonus was 50% of Mr. Kopfli's annualized salary and was to be based on achievement of performance goals and objectives agreed to by Mr. Kopfli and the board of directors in January of each year. The board of directors was to increase the bonus in recognition of performance in excess of the performance objectives. Any bonus would have only been paid if Mr. Kopfli remained employed on the date of payment, which would have been no later than March 15 of the year following the year to which the bonus relates. Any bonus for 2022 would have been payable solely in the board of directors' discretion.

Pursuant to Mr. Kopfli's employment agreement, in the event he was involuntarily terminated by the Company other than for "Cause" or if he resigns for "Good Reason," he was entitled to receive (i) six months of salary at the same rate existing immediately prior to his termination, (ii) his target bonus, if performance goals and objectives had been established for the year and prorated for the period of service, and (iii) six months of additional vesting credit with respect to any outstanding time-based equity awards. "Cause" and "Good Reason" are each defined in the employment agreement.

Finally, Mr. Kopfli agreed to certain non-solicitation and non-competition provisions for a period of 12 months following termination and to certain confidentiality obligations. Additional terms and conditions are set forth in the employment agreement.

On November 27, 2023, Mr. Kopfli was removed from our board of directors by our stockholders having a majority of the number of votes necessary to take such action. Mr. Kopfli was then terminated from his position as Vice Chairman and Chief Strategy Officer by the Company for "Cause", as defined in the employment agreement, effective December 1, 2023.

Camden Capital LLC

We entered into a Consultant Agreement with Camden Capital LLC ("Camden"), dated January 10, 2023 (the "Consultant Agreement"). This Consultant Agreement replaced an agreement with Mr. Francis Knuettel II dated June 2, 2022 and pursuant to which, Camden agreed to provide the services of Mr. Knuettel, who was to serve as our Chief Financial and Strategy Officer, Treasurer and Secretary.

Under the Consultant Agreement, Camden accrued a consulting fee for the period June 6, 2022 through August 31, 2022 of $10,000 per month and effective September 1, 2022, began to accrue a consulting fee of $20,000 per month, payable in cash at the rate of $5,000 per month (a minimum of $1,125 per week), with the remainder accrued. All accrued consulting fees are payable as of the earliest of a sale or liquidation of the Company, the Company's bankruptcy or three days after Post-registration Approval. The Consultant Agreement provides for the following equity awards to Camden: (i) an option, awarded as of January 10, 2023, to acquire 200,000 shares of our Common Stock, vesting quarterly over 10 quarters and beginning October 1, 2022, with the option having an exercise price equal to the fair market value of our Common Stock on the date of grant and expiring on the 10th anniversary of the date of grant; (ii) an option, awarded as of January 10, 2023, to acquire 25,000 shares of our Common Stock, vesting 100% upon the sooner of the sale of the Company or Post-registration Approval, with the option having an exercise price equal to the fair market value of our Common Stock on the date of grant and expiring on the 10th anniversary of the date of grant; and (iii) a RSU, awarded as of January 10, 2023, of 150,000 shares of our Common Stock, vesting 100% on the day after the first trading window that opens after Post-registration Approval.

The Consultant Agreement contemplates an additional consulting fee, as determined by the board of directors. The potential additional consulting fee is 50% of the annualized consulting fee and will be based on achievement of performance goals and objectives established by the board of directors in concert with Mr. Knuettel in January of each year. The board of directors may increase the potential additional consulting fee in recognition of performance in excess of the performance objectives. Any amount shall only be paid if Camden continues to provide consulting services to the Company as of the date of payment, which will be no later than March 15 of the year following the year to which the additional consulting fee relates. Any additional consulting fee for 2022 is payable solely in the board of directors' discretion.

Pursuant to the Consultant Agreement, in the event the relationship with Camden is involuntarily terminated by the Company other than for "Cause" or if Camden terminates the relationship for "Good Reason," Camden is entitled to receive (i) six months of consulting fees at the same rate existing immediately prior to termination, (ii) a potential additional consulting fee, if performance goals and objectives have been established for the year and prorated for the period of service, and (iii) six months of additional vesting credit with respect to any outstanding time-based equity awards. "Cause" and "Good Reason" are each defined in the Consultant Agreement.

Finally, Camden and Mr. Knuettel agree to certain non-solicitation and non-competition provisions for a period of 12 months following termination of the relationship and to certain confidentiality obligations. Additional terms and conditions are set forth in the Consultant Agreement.

On June 23, 2023, we amended and restated the Consultant Agreement by entering into an Amended and Restated Consultant Agreement with Camden whereby the RSU for 16,667 shares of Common Stock was cancelled, and we agreed to grant Camden an option to acquire 27,777 shares of Common Stock within 30 days of the closing of the IPO. As of June 23, 2023, such RSU for 16,667 shares of our Common Stock had not vested, and no expense was recorded on the Company's financial statements. In addition, from and after June 1, 2023, the consulting fee will be paid in cash by the Company. No other material changes were made to the Consultant Agreement.

Eric Lang

We are a party to an employment agreement with Eric Lang, effective May 15, 2023. Pursuant to such agreement, Mr. Lang agreed to serve as our Chief Medical Officer, in consideration for an annualized salary of $400,000. The employment agreement provides that Mr. Lang receive an option to acquire 218,000 shares of our Common Stock, vesting quarterly over 12 quarters and beginning August 15, 2023. This option shall have an exercise price equal to the fair market value of our Common Stock on the date of grant and shall expire on the 10th anniversary of the date of grant. The option was awarded as of May 15, 2023. The employment agreement contemplates an annual bonus, as determined by the board of directors. The target bonus is 50% of Mr. Lang's annualized salary and will be based on achievement of performance goals and objectives determined by our Chief Executive Officer. The Chief Executive Officer may increase the bonus in recognition of performance in excess of the performance objectives. Any bonus will be paid if Mr. Lang remains employed on the date of payment, which will be no later than March 15 of the year following the year to which the bonus relates. In addition, the employment agreement contemplates annual equity bonus. The board of directors may, in its sole discretion, and for so long as Mr. Lang remains an employee, make an annual discretionary bonus award of an option to acquire up to 32,000 additional shares of Common Stock of the Company. Any such option shall vest in equal increments on a quarterly basis, beginning one quarter after the date of grant, with the final vesting date on the third anniversary of the date of grant. The option shall have an exercise price equal to the fair market value of our Common Stock on the date of grant and shall expire on the 10th anniversary of the date of grant.

Pursuant to Mr. Lang's employment agreement, in the event he is involuntarily terminated by the Company other than for "Cause" or if he resigns for "Good Reason," he is entitled to receive (i) six months of salary at the same rate existing immediately prior to his termination, (ii) 50% of his annualized salary, prorated from January 1 of the year of termination and through the date of termination, (iii) vesting of all outstanding options with time-based vesting, and (iv) coverage of 18 months of group medical, dental and/or vision benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, if he elects to continue such benefits. "Cause" and "Good Reason" are each defined in the employment agreement.

Finally, Mr. Lang agreed to certain non-solicitation and non-competition provisions for a period of 12 months following termination and to certain confidentiality obligations. Additional terms and conditions are set forth in the employment agreement.

Equity and Equity-Based Plans

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding the outstanding equity awards of our named executive officers during the year ended December 31, 2023.

	Option Awards					Stock Awards			
Name and Principal Position	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date	Number of shares of Common Stock Unvested	Market Value of shares of Common Stock Unvested	Equity Incentive Plan Awards: Number of Unearned Unvested Shares	Equity Incentive Plan Awards: Market or Payout Value of Unearned Unvested Shares
Christian Kopfli Former Chief Executive Officer [1]	100,000	100,000	—	$ 2.52	09/30/2032	—	$ —	—	$ —
Francis Knuettel II, Chief Executive Officer and Chief Financial Officer	100,000	375,000	—	$ 2.52	09/30/2032	—	$ —	—	$ —
Eric Lang, Chief Medical Officer	36,333	181,667	—	$ 2.52	05/15/2033	—	$ —	—	$ —

(1) Mr. Kopfli stepped down as Chief Financial Officer with the hiring of Mr. Knuettel, effective June 10, 2022. In addition, in July 2023, Mr. Knuettel assumed the role of Interim Chief Executive Officer and stepped down as Chief Strategy Officer, and Mr. Kopfli was appointed Vice Chairman and Chief Strategy Officer. On December 1, 2023, the Company terminated Mr. Kopfli as Vice Chairman and Chief Strategy Officer.

Equity Incentive Plans

The Chromocell Therapeutics Corporation 2023 Equity Incentive Plan

On January 10, 2023, our board of directors adopted and submitted for stockholder approval the 2023 Plan, which 2023 Plan was later approved by the Company's stockholders. On February 15, 2023, we amended the 2023 Plan to increase the number of shares available for issuance thereunder to 444,444. The following summary of the material features of the 2023 Plan is qualified in its entirety by reference to the complete text of the 2023 Plan, a copy of which is filed with this Report. The 2023 Plan will terminate on January 10, 2033, in accordance with its terms, although, awards outstanding under the 2023 Plan will continue to be governed by their existing terms after the 2023 Plan's expiration.

Share Reserve. We have reserved 444,444 shares of our Common Stock for issuance under the 2023 Plan. Unissued shares of Common Stock subject to awards that fail to settle, vest or be fully exercised prior to expiration or other termination shall again become available for grant under the terms of the 2023 Plan.

Administration. Our board of directors currently administers the 2023 Plan. The compensation committee of our board of directors administers the 2023 Plan. The administrator has complete discretion to make all decisions relating to the 2023 Plan and outstanding awards.

Eligibility. Key employees, non-employee members of our board of directors and other persons who render services of special importance to our management, operation or development are eligible to participate in the 2023 Plan.

Types of Awards. The 2023 Plan provides for the following types of awards granted with respect to shares of our Common Stock:

- incentive and nonqualified stock options to purchase shares of our Common Stock;
- stock appreciation rights, whether settled in cash or our Common Stock;
- direct awards or sales of shares of our Common Stock, with or without restrictions; and
- restricted stock units.

The recipient of an award under the 2023 Plan is referred to as a participant.

Options. The administrator may grant incentive stock options ("ISOs") and nonqualified stock options ("NSOs") under the 2023 Plan. The administrator determines the number of shares of our Common Stock subject to each option, its exercise price, its duration and the manner and time of exercise; provided, however, that no option may be issued under the 2023 Plan with an exercise price that is less than the fair market value of our Common Stock as of the date the option is granted, and no option issued as an ISO will have a duration that exceeds ten years. ISOs may be issued only to our employees or employees of our corporate subsidiaries, and in the case of a more than ten percent stockholder, must have an exercise price that is at least 110% of the fair market value of our Common Stock as of the date the option is granted, and may not have a duration of more than five years.

The administrator, in its discretion, may provide that any option is subject to vesting limitations that make it exercisable during its entire duration or during any lesser period of time.

The exercise price of an option may be paid in cash, by delivery of a recourse promissory note secured by the Common Stock acquired upon exercise of the option (except that such a loan would not be available to any of our executive officers or directors), by means of a "cashless exercise" procedure in which a broker transmits to us the exercise price in cash, either as a margin loan or against the optionee's notice of exercise and confirmation by us that we will issue and deliver to the broker stock certificates for that number of shares of Common Stock having an aggregate fair market value equal to the exercise price, or agrees to pay the exercise price to us in cash upon our receipt of stock certificates, by delivery of shares of our Common Stock already owned by the optionee, by a "net exercise" in the case of an NSO or by any combination of the methods listed.

Stock Appreciation Rights ("SARs"). The administrator may also grant SARs to participants on such terms and conditions as it may determine. SARs may be granted separately or in connection with an option. No SAR may be issued under the 2023 Plan with an exercise price that is less than the Fair Market Value of our Common Stock as of the date the SAR is granted, and no SAR will have a duration that exceeds ten years. Upon the exercise of an SAR, the participant is entitled to receive payment equal to the excess of the fair market value, on the date of exercise, of the number of shares of Common Stock for which the SAR is exercised over the exercise price for the Common Stock under a related option or, if there is not a related option, over an amount per share stated in the agreement setting forth the terms and conditions of the SAR.

Payment to the participant may be made in cash or other property, including Common Stock, in accordance with the provisions of the SAR agreement.

Stock Grants. The administrator may make an award in one or more of the following forms of stock grant. Stock grants (including restricted stock units and performance units after settlement) generally will provide the participant with all of the rights of a stockholder of ours, including the right to vote and to receive payment of dividends.

Stock grant without restriction. The administrator may make a stock grant without any restrictions.

Restricted stock and RSUs. The administrator may issue shares of our Common Stock with restrictions determined by the administrator in its discretion. Restrictions could include conditions that require the participant to forfeit the shares in the event that the participant ceases to provide services to us or any of our affiliates thereof before a stated time. RSUs are similar to restricted stock except that no shares are actually issued to the participant on the RSU grant date. Rather, and provided all applicable restrictions are satisfied, shares of Common Stock are generally delivered at settlement of the award. The period of restriction, the number of shares of restricted stock or the number of RSUs granted, the purchase price, if any, and such other conditions and/or restrictions as the administrator may establish will be set forth in an award agreement. Participants holding RSUs will not have voting rights or other rights as a stockholder until any shares related to the RSU are issued. After all conditions and restrictions applicable to restricted shares and/or RSUs have been satisfied or have lapsed, shares of restricted stock will become freely transferable and RSUs may be settled in cash, in shares of our Common Stock or in some combination of cash and shares of our Common Stock, as determined by the administrator and stated in the award agreement.

Performance shares and performance share units ("PSUs"). With respect to an award of performance shares and/or PSUs, the administrator will establish performance periods and performance goals. The extent to which a participant achieves their performance goals during the applicable performance period will determine the value and/or the number of performance shares and/or PSUs earned by such participant. Payment of earned performance shares and/or PSUs will be in cash, shares of our Common Stock or some combination of cash and shares of our Common Stock, as determined by the administrator and stated in the award agreement.

Other awards. The administrator may issue other types of equity-based or equity-related awards under the 2023 Plan, on such terms and conditions as the administrator shall determine in its discretion.

Dividends. Participants holding restricted stock and performance shares will be entitled to receive dividends on our shares, provided that in the discretion of the administrator, participants will not be entitled to dividends with respect to unvested restricted stock and performance shares until the stock or shares vest, respectively. Dividend equivalent units may, but are not required to, be issued with respect to RSUs or PSUs and may be paid in cash, additional shares of our Common Stock or a combination on the date the shares are delivered, all as determined by the administrator and stated in the award agreement.

Effect of certain corporate transactions. In the event of a stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution on our Common Stock other than an ordinary cash dividend, the administrator shall make equitable adjustments to awards as it, in its sole discretion, deems appropriate. In the case of (1) a merger or consolidation of the Company with or into another entity pursuant to which all of our Common Stock is cancelled or converted into or exchanged for the right to receive cash, securities or other property, (2) any transfer or disposition of all of our Common Stock for cash, securities or other property pursuant to a share exchange or other transaction, (3) the sale or other disposition of all or substantially all of the Company's assets or (4) any liquidation or dissolution of the Company, the administrator may take any of a number of actions including providing for the assumption of awards, the termination of awards (with advance notice permitting exercise), Awards to become exercisable at or prior to the event, the liquidation of awards or any combination of the foregoing.

Amendments to the 2023 Plan. Our board of directors may amend, suspend or terminate the 2023 Plan in whole or in part at any time provided that stockholder approval shall be required to the extent necessary under the rules applicable to ISOs or under NYSE American or other applicable securities exchange rules.

The administrator may, without stockholder approval, amend the 2023 Plan as necessary to enable awards to qualify for favorable foreign tax, securities or other treatment in the case of a participant who is subject to a jurisdiction outside the United States.

Amendments or Termination. The administrator may at any time amend, suspect or terminate the 2023 Plan, subject to stockholder approval in the case of an amendment if the amendment increases the number of shares available for issuance or materially changes the class of persons eligible to receive incentive stock options. The 2023 Plan will terminate automatically ten years after the later of the date when our board of directors adopted the plan or the date when our board of directors most recently approved an increase in the number of shares of Common Stock reserved thereunder which was also approved by our stockholders, and as noted above, any awards outstanding under the 2023 Plan upon termination will remain outstanding and will continue to be governed by their existing terms.

On January 10, 2023, pursuant to the 2023 Plan, we granted: (a) options to purchase up to an aggregate of 141,667 shares of Common Stock to employees and directors and (b) 16,667 RSUs to employees. On March 9, 2023, pursuant to the 2023 Plan, we granted an option to purchase up to 15,000 shares of Common Stock to a director. On June 23, 2023, we granted options to acquire 52,000 shares of Common Stock to employees (inclusive of options that have not yet been granted but the Company has agreed to grant in connection with the closing of the IPO) and canceled an RSU for 16,667 shares issued to an employee on January 10, 2023.

The offers and sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act, as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the above securities represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof.

Director Compensation for Fiscal Year 2023

We have not implemented a formal policy with respect to compensation payable to our non-employee directors. From time to time, we have granted equity awards to attract individuals to join our board of directors and for their continued service thereon. In 2023, independent directors received $0 in cash compensation. In addition, in 2023 directors were granted options to purchase 81,668 shares of Common Stock at fair market value as of the date of issuance, expiring ten years from issuance. In addition, we reimburse our directors for expenses associated with attending meetings of our board of directors and its committees. Our board of directors is still in the process of considering the non-employee director compensation policy.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Stock Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Todd Davis	—	—	748,038	—	—	—	748,038
Ezra Friedberg	—	—	374,019	—	—	—	374,109
Richard Malamut	—	—	374,019	—	—	—	374,019
Chia-Lin Simmons	—	—	336,606	—	—	—	336,606

(1) Amounts reflect the aggregate grant date fair value of the stock options granted to each named executive officer during the fiscal year ended December 31, 2022 and 2023, as computed in accordance with Financial Accounting Standards Board ASC 718.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth certain information regarding the beneficial ownership of our capital stock as of April 10, 2024 by (a) each person, or group of affiliated persons, who is known to us to own beneficially 5% or more of our outstanding equity securities; (b) each of our directors; (c) each of our named executive officers; and (d) all of our named executive officers and directors as a group. Except as otherwise indicated in the footnotes below, we believe, based on the information provided to us, that all persons listed below have sole voting power and investment power with respect to their shares of Common Stock or other equity securities that they beneficially own, subject to community property laws where applicable.

For purposes of this table, a person or group of persons is deemed to have "beneficial ownership" of any shares of Common Stock or other equity securities of the Company that such person has the right to acquire within sixty (60) days of April 10, 2024. For purposes of computing the percentage of outstanding shares of our Common Stock or other equity securities of the Company held by each person or group of persons named above, any shares that such person or persons has the right to acquire within sixty (60) days of April 10, 2024 is deemed to be outstanding, but is not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. The inclusion herein of any shares of Common Stock or other equity securities of the Company listed as beneficially owned does not constitute an admission of beneficial ownership. Unless otherwise identified, the address of our directors and executive officers is 4400 Route 9 South, Suite 1000, Freehold, NJ 07728.

Name of and Address of Beneficial Owner(1):	Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned
Directors and executive officers		
Francis Knuettel II (2)	177,070	3.0%
Ezra Friedberg (3)	529,054	9.0%
Todd Davis (4)	68,060	1.2%
Richard Malamut (5)	8,335	*%
Chia-Lin Simmons (6)	8,335	*%
Eric Lang (7)	8,074	*%
All executive officers and directors as a group (6 persons)	768,367	13.1%
5% or greater stockholders:		
Chromocell Corporation (8)	1,093,854	18.6%
Boswell Prayer Ltd (9)	471,592	8.0%
Motif Pharmaceuticals Ltd. (10)	483,406	8.2%
Balmoral Financial Group LLC (11)	520,719	8.9%
AME Equities LLC (12)	369,178	6.3%
Aperture Healthcare Ventures Ltd. (13)	443,071	7.6%
Benuvia Operations, LLC (15)	384,226	6.5%

* Less than 1%

(1) Except as otherwise indicated, the persons named in the table above have sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them.

(2) For Mr. Knuettel, includes 15,561 shares of Common Stock underlying stock options that are currently exercisable or exercisable within 60 days of April 10, 2024 which are exercisable for shares of Common Stock at a price of $22.68 per share. It also includes an additional 2,778 shares of Common Stock underlying stock options exercisable upon the closing of the IPO and 27,778 shares of Common Stock underlying stock options that will be issued and will become exercisable within 30 days of the close of the IPO, neither of which have been granted to date and 130,953 shares held by the Lara Knuettel Revocable Trust. All stock options are held of record by Camden. Mr. Knuettel serves as Managing Member of Camden and co-trustee, with individual dispositive power of the Lara Knuettel Revocable Trust, and accordingly, may be deemed to beneficially own the shares of Common Stock owned directly by Camden and the Lara Knuettel Revocable Trust.

(3) For Mr. Friedberg, includes 8,335 shares of Common Stock issuable upon the exercise stock options held by Mr. Friedberg, which are exercisable for shares of Common Stock at a price of $22.68 per share. In addition, Mr. Friedberg serves as a manager of Balmoral Financial Group LLC ("Balmoral").

(4) For Mr. Davis, includes 16,670 shares of Common Stock issuable upon the exercise of stock options held by Mr. Davis, which are exercisable for shares of Common Stock at a price of $22.68 per share, 22,223 shares of Common Stock issuable upon the exercise of stock options held by Mr. Davis, which are exercisable for shares of Common Stock at a price of $22.68 per share and an additional 29,167 shares of Common Stock issued in a private placement in full satisfaction of the Company's obligations under the Director Note.

(5) For Mr. Malamut, includes 8,335 shares of Common Stock issuable upon the exercise of stock options held by Mr. Malamut, which are exercisable for shares of Common Stock at a price of $22.68 per share.

(6) For Ms. Simmons, includes 8,335 shares of Common Stock issuable upon the exercise of stock options held by Ms. Simmons, which are exercisable for shares of Common Stock at a price of $22.68 per share.

(7) For Mr. Lang, includes 5,592 shares of Common Stock issuable upon the exercise of stock options held by Mr. Lang, which are exercisable for shares of Common Stock at a price of $22.68 per share.

(8) For Chromocell Corporation, the shares of Common Stock beneficially owned includes 346,667 shares of Common Stock issuable upon the conversion of 2,600 shares of Series C Preferred Stock at $7.50 per share, or 125% of the price per IPO Share, based on the IPO price per IPO Share of $6.00. Christian Kopfli has sole voting and dispositive power over the shares held by Chromocell Corporation. The principal executive office of Chromocell Corporation is 685 US Highway One, North Brunswick, NJ 08902.

(9) Rochelle Gross has sole voting and dispositive power over the shares held by Boswell Prayer Ltd. The principal executive office of Boswell Prayer Ltd. is 145 Adelaide Street West, Toronto ON M5H 4E5, Canada.

(10) None of the directors of that board of directors has sole voting or dispositive power with respect to the shares of Common Stock held by Motif Pharmaceuticals Ltd. The principal executive office of Motif Pharmaceuticals Ltd. is 25 and 28 North Wall Quay, Dublin 1, Ireland.

(11) Ezra Friedberg has sole voting and dispositive power over the shares held by Balmoral. The principal executive office of Balmoral is 106 Court Road, Suite 202, Baltimore, MD 21208.

(12) Ruth Friedman has sole voting and dispositive power over the shares held by AME Equities LLC. The principal executive office of AME Equities LLC is 3012 Luke Crossing Drive, Charlotte, NC 28226.

(13) None of the directors of that board of directors has sole voting or dispositive power with respect to the shares of Common Stock held by Aperture Healthcare Ventures Ltd. The principal executive office of Aperture Healthcare Ventures Ltd. is 970 Lawrence Ave W. Suite 904, Toronto, ON M6A 3B6, Canada.

(14) Darwin Richardson has sole voting and dispositive power over the shares held by Benuvia. The principal executive office of Benuvia is 3950 N. Mays Street Round Rock, TX 78665.

Securities Authorized for Issuance under Equity Compensation Plans

Plan Category	Number of Securities to Be Issued upon Exercise of Outstanding Options, Warrants and Rights (2)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (2)	Number of Securities Remaining Available for Future Issuance under the Plan (excluding securities reflected in column (a) (2))
	(a)	(b)	(c)
Equity compensation plans approved by security holders (1)	208,672	$ 22.68	235,772
Equity compensation plans not approved by security holders			
Total			235,772

(1) Represents the shares of Common Stock authorized for issuance under the 2023 Plan. In February 2024, the board of directors approved an amendment to the 2023 Plan, subject to stockholder approval which was subsequently obtained. An aggregate of 3,000,000 shares were originally authorized for issuance under the 2023 Plan, and after the amendment and our Reverse Stock Split in connection with the IPO, an aggregate of 444,444 shares have been authorized under the 2023 Plan. As of April 10, 2024, options to purchase an aggregate of 208,672 shares of our Common Stock at exercise prices of $22.68 per share, with a weighted-average exercise price of $22.68 per share, were outstanding under the 2023 Plan, with 235,772 shares of our Common Stock remaining available for future issuance. Unissued shares subject to awards that expire, are forfeited, or are cancelled will again become available for issuance under the 2023 Plan.

(2) As of December 31, 2023.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Transactions with Related Parties

The following is a summary of transactions among related parties that occurred since the Company's incorporation, and any ongoing related party relationships:

In May 2021, Chromocell Holdings, the Company and Flamands International Holdings LLC ("Flamands") commenced negotiations regarding a three-party agreement whereby Chromocell Holdings would spin off assets and liabilities associated with its therapeutics operations to the Company and Flamands would provide funding to the Company. As the parties contemplated various transactional structures, an agreement was never effectuated because significant details concerning the assumption of liabilities were never finalized. Chromocell Holdings instead provided multiple advances to the Company for its operations from May 2021 through August 2022. At December 31, 2021, all amounts previously received from Chromocell Holdings by the Company were recorded as advances payable on the Company's financial statements.

On August 10, 2022, the Company and Chromocell Holdings entered into the Contribution Agreement effecting (1) the contribution by Chromocell Holdings to the Company of assets related to Chromocell Holdings' therapeutics business, which we transferred to the Company (the "Therapeutics Business"), including all intellectual property secrets related to Chromocell Holdings' NaV1.7 program and its clinical-stage CC8464 lead compound, (2) assumption by the Company of direct liabilities related to Chromocell Holdings' historical Therapeutics Business in the amount of $1,556,323 as well as a cash payment by the Company to Chromocell Holdings of $597,038 within three business days of the closing of the IPO and (3) the issuance by the Company to Chromocell Holdings of 1,111,112 shares of its Common Stock and 600,000 shares of Series A Preferred Stock.

On August 2, 2023, we entered into the Holdings Side Letter to the Contribution Agreement. Pursuant to the Holdings Side Letter, upon closing of the IPO: (a) Chromocell Holdings re-assumed all $1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings waived the Company's obligations to make a cash payment in the amount of $0.6 million to Chromocell Holdings, and (c) in consideration thereof, we issued to Chromocell Holdings 2,600 shares of Series C Preferred Stock.

On April 17, 2023, Chromocell Holdings forfeited 133,745 shares of Common as Chromocell Holdings did not fund its pro rata allocation in the April Bridge Financing, per the terms governing the April Bridge Financing.

On December 6, 2022, the Company and Mr. Todd Davis, one of our directors, entered into the Director Note for $175,000. The Director Note has an original issuance discount of $75,000 and matures on December 31, 2023, or, if earlier to occur, upon the closing of an underwritten offering of securities resulting in at least $15 million in gross proceeds. Mr. Davis, as lender, has the right but not the obligation to subscribe to the underwritten offering by presenting the Director Note in whole or in part to purchase such securities as legal tender therefor, on a dollar-for-dollar basis based upon the offering price of such securities to the public. The Director Note bears no interest except in the case of certain events of default. As of December 31, 2023, there was an unamortized debt discount of $0. On December 28, 2023, we entered into an amendment to the Director Note, which extended the maturity date to February 29, 2024.

On April 17, 2023, we entered into the April Bridge Financing for working capital purposes with various accredited investors, all of whom are pre-existing stockholders, including Chromocell Holdings, Boswell Prayer Ltd., Motif Pharmaceuticals Ltd, Aperture Healthcare Ventures Ltd., MDB Merchants Park LLC, Balmoral and AME EQUITIES LLC (each a related party based on share ownership in excess of 5% or resulting from a principal at one of the entities being on the Company's board of directors) in the aggregate principal amount of $389,757, after giving effect to the Representative Affiliate Transactions. During the year ended December 31, 2023, the Company received an aggregate of $303,651 in Advances prior to the close of the April Bridge Financing from certain of the participating investors. Such Advances accrued interest at a rate of eight percent (8%) per annum until close of the April Bridge Financing on April 17, 2023, for a total of $19,323 in aggregate interest on all Advances during the year ended December 31. The April Bridge Financing consists of senior secured convertible notes that had a maturity date of October 17, 2023. On October 12, 2023, we entered into a first amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 1, 2023. On October 24, 2023, we entered into a second amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 14, 2023. On November 13, 2023, we entered into a third amendment to the senior secured convertible notes in the April Bridge Financing, which further extended the maturity of the notes to February 29, 2024. Such notes accrue interest on the unpaid principal amount at a rate of eight percent (8%) per annum and will automatically convert into 87,109 shares of Common Stock in connection with the IPO at a twenty percent (20%) discount to the price per IPO Share (based on the IPO price of $6.00 per IPO Share). The senior secured convertible notes issued in the April Bridge Financing are secured by a security interest in all of our assets (including our patents and intellectual property licenses). In connection with the April Bridge Financing, on April 17, 2023, we also entered into a securities purchase agreement with holders of the notes, pursuant to which we are required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock received by holders of the notes upon conversion of such notes.

On September 1, 2023, we entered into the September Bridge Financing with various accredited investors, certain of which are pre-existing stockholders, including Aperture Healthcare Ventures Ltd., MDB Merchants Park LLC, Balmoral and AME EQUITIES LLC (each a related party based on share ownership in excess of 5% or resulting from a principal at one of the entities being on the Company's board of directors) in the aggregate principal amount of $197,421, after giving effect to the Representative Affiliate Transactions. The September Bridge Financing consists of senior secured convertible notes that have a maturity date of March 1, 2024. Such notes accrue interest on the unpaid principal amount at a rate of eight percent (8%) per annum and automatically converted into shares of Common Stock in connection with the IPO at a twenty percent (20%) discount to the price per IPO Share plus 549 Bonus Shares (43,385 shares, based on the IPO price of $6.00 per IPO Share). The senior secured convertible notes issued in the September Bridge Financing are secured by a security interest in all of our assets (including our patents and intellectual property licenses). In connection with the September Bridge Financing, on September 1, 2023, we also entered into a securities purchase agreement with holders of the notes, pursuant to which we are required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock received by holders of the notes upon conversion of such notes. Additionally, we entered into a subordination and intercreditor agreement, effective September 1, 2023, with the holders of the senior secured convertible notes issued in the April Bridge Financing, pursuant to which those notes and certain liens of the Company will be subordinated to the rights of the holders of the notes issued in the September Bridge Financing.

On October 12, 2023, we and four existing investors entered into the October Promissory Notes with an aggregate face amount of $210,000 and an aggregate purchase price of $175,000. The October Promissory Notes mature on November 12, 2023 or, if earlier to occur, upon the closing of the IPO. The October Promissory Notes bear no interest except in the case of certain events of default. On November 7, 2023, we amended and restated the October Promissory Notes to extend the maturity dates of the October Promissory Notes to November 17, 2023. On November 13, 2023, we amended and restated the October Promissory Notes to further extend the maturity dates of the Promissory Notes to February 29, 2024. The October Promissory Notes were repaid on February 26, 27 and 28, 2024.

On November 22, 2023, we commenced the Rights Offering pursuant to which we distributed Subscription Rights to each holder of our Common Stock held as of the Rights Offering Record Date. The Subscription Rights could be exercised at any time during the subscription period, which commenced on November 22, 2023 and expired at 5:00 p.m., Eastern Standard Time, on December 1, 2023. The Subscription Rights were offered to all of our pre-existing stockholders, including Aperture Healthcare Ventures Ltd., MDB Merchants Park LLC, Balmoral and AME EQUITIES LLC (each a related party based on share ownership in excess of 5%, or resulting from a principal at one of the entities being on the Company's board of directors), and each participated and exercised their Subscription Rights to purchase an aggregate of 1,221,338 shares of Common Stock at the Subscription Price. In addition, we distributed to Mr. Knuettel, our Chief Executive Officer and Chief Financial Officer, and Mrs. Lara Knuettel c/o The Lara H. Knuettel Revocable Trust, a trust for which Mr. Knuettel and his wife are co-trustees (the "Knuettel Trust"), and at no charge to them, additional non-transferable Subscription Rights to purchase up to an aggregate 158,731 shares of our Common Stock in the Rights Offering at the same Subscription Price. On December 27, 2023, the Knuettel Trust made a charitable donation of 27,778 of those shares to Temple Israel of the City of New York. Also on December 27, 2023, AME EQUITIES LLC made a charitable donation of 87,778 of its shares to Ballantyne Jewish Center, Inc. Upon the closing of the Rights Offering, we issued an aggregate of 2,442,468 shares of our Common Stock and received aggregate net proceeds of $246,201, after giving effect to the Representative Affiliate Transactions, which we used primarily for general corporate purposes and expenses associated with our IPO.

On December 23, 2023, we entered into the Benuvia License Agreement for the Spray Formulations, diversifying our pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The Diclofenac Spray Formulation is patented and has started clinical development in human volunteers. Preliminary pharmacokinetics suggest that this formulation may have a faster onset of action than oral Diclofenac tablets. Diclofenac is an NSAID that is also marketed under additional brand names including Voltaren and Cataflam in its pill form. Rizatriptan, whose brand name is Maxalt, is used for the acute treatment of migraines as a pill. By a number of clinical measures it is thought to be superior to Sumatriptan. A sublingual formulation of Rizatriptan may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea as a result of the migraine headache. Ondansetron is an anti-emetic that is available in oral and intravenous form. An Ondansetron sublingual spray formulation may potentially have a faster onset of action than an oral form and may be easier to tolerate than swallowing a pill when patients are experiencing nausea. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations and we will purchase the Spray Formulations exclusively from Benuvia, pursuant to the Benuvia Supply Agreement. The initial sale price per unit for each Spray Formulation payable by us to Benuvia pursuant to the Benuvia Supply Agreement shall be subject to good faith negotiations; provided that the initial price for each Spray Formulation and the price for each Spray Formulation during the term of the Benuvia License Agreement in no event shall be less than Benuvia's cost of manufacturing the respective Spray Formulation plus a gross margin to Benuvia. The price for each Spray Formulation shall be subject to an annual increase in amounts equal to the percentage change in the Producer Price Index, Pharmaceutical Preparations as published by the U.S. Department of Labor, Bureau of Labor Statistics.

Under the terms of the Benuvia License Agreement, we obtained exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations. In connection with the Benuvia License Agreement, we agreed to pay Benuvia a six and one-half percent (6.5%) royalty on net sales of the Spray Formulations for a period of up to 15 years from the date of the first commercial sale of the Spray Formulations. To date, we have paid $0 to Benuvia as royalty on net sales of the Spray Formulations. Pursuant to the Benuvia Stock Issuance Agreement, we issued to Benuvia 384,226 shares of our Common Stock, which may be offered and sold pursuant to the Resale Prospectus. Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, which is capped not to exceed a specific gross margin for Benuvia, and we have a most favored nation rate on development and regulatory services.

Under the Benuvia License Agreement, we will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations. Further, we have the right to request a bid from a third party to manufacture the Spray Formulations once each year.

The Benuvia License Agreement contains standard termination provisions. The Benuvia License Agreement may be terminated in its entirety, on a Spray Formulation by Spray Formulation basis, and by country by county for a material breach not cured within sixty (60) days after written notice thereof. If we breach any of our payment obligations under the terms of the Benuvia License Agreement that are not the subject of a good faith dispute and are not cured within twenty (20) business days following notice thereof, Benuvia may terminate the Agreement upon written notice to us. We also have the right to terminate the Benuvia License Agreement in the event we determine, in our reasonable business judgment, that (i) any of the Spray Formulations will not be differentiated from oral tablets to result in a financially viable product or (ii) after having discussed a Spray Formulations with the FDA, we determine in our reasonable business judgment, that the cost of development of such Spray Formulation would exceed any reasonable forecast of a positive financial return. In the event we terminate the License Agreement, the parties will negotiate in good faith a license agreement to any improvements we made to the Spray Formulations, including any clinical trial data, and Benuvia will pay us a pre-determined royalty for such license. Mr. Davis, one of our directors, serves as the Chairman and Chief Executive Officer of Benuvia Holdings, LLC, which is the ultimate parent company of Benuvia.

On February 8, 2024, we and certain affiliates of the Representative entered into the Bridge Financing Note Amendments. Under the Bridge Financing Note Amendments, both notes issued in the April Bridge Financing and the September Bridge Financing had a maturity date of March 1, 2024, and the full principal amount of both notes and any accrued interest thereon was payable solely in cash upon the consummation of the IPO. Both notes had an annual interest rate of eight percent (8%), which accrued daily, and was calculated on the basis of a 360-day year (consisting of twelve 30 calendar day periods).

On February 10, 2024, we entered into the Stock Rescission Agreement with certain affiliates of the Representative, pursuant to which we rescinded 111,129 shares of our Common Stock held by such affiliates of the Representative and agreed to refund an aggregate of $91,512.53 paid by such affiliates of the Representative in consideration therefor within 30 days of the effective date of the Stock Rescission Agreement.

Review, Approval or Ratification of Transactions with Related Parties

We have adopted a written related-person transactions policy that provides that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our Common Stock and any members of the immediate family of the foregoing persons, are not permitted to enter into a material related-person transaction with us without the review and approval of our audit committee, or a committee composed solely of independent directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. Such policy provides that any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our Common Stock or with any of their immediate family members or affiliates, in which the amount involved exceeds the lesser of (i) $120,000 or (ii) one percent of the average of the Company's total assets at year-end for the last two fiscal years, will be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, we expect that our audit committee will consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

Item 14. Principal Accountant Fees and Services.

Marcum LLP is our independent registered public accounting firm and performed the audits of our financial statements for the years ended December 31, 2023 and 2022. The following table sets forth all fees billed or to be billed for such periods:

	2023	2022
Audit fees (1)	$ 164,229	$ 387,030
Audit-related fees (2)	156,346	12,051
Tax fees (3)	—	—
All other fees (4)	43,490	—
Total	$ 364,065	$ 399,081

(1) "Audit fees" include fees for professional services rendered in connection with the audit of our annual financial statements, review of our quarterly condensed financial statements and advisory services on accounting matters that were addressed during the annual audit and quarterly review. This category also includes fees for services that were incurred in connection with statutory and regulatory filings or engagements, such as consents and review of documents filed with the SEC.

(2) “Audit-related fees” include fees billed for professional services rendered that are reasonably related to the performance of the audit or review of our financial statements including subscription for the online library of accounting research literature and are not reported under “Audit Fees”.

(3) “Tax fees” include fees for tax compliance. Tax compliance fees encompass a variety of permissible services, including technical tax advice related to federal and state income tax matters, and assistance with tax audits.

(4) “All other fees” include fees for the bring down and comfort letters associated with the IPO as well as work done in evaluating the Contribution Agreement.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

Our Audit Committee pre-approves all audit and non-audit services provided by the independent auditors prior to the engagement of the independent auditors with respect to such services. The chairman of our Audit Committee has been delegated the authority by such committee to pre-approve interim services by the independent auditors other than the annual audit. The chairman of our Audit Committee must report all such pre-approvals to the entire Audit Committee at the next committee meeting.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Report:

(1) Financial Statements:

The audited balance sheets of the Company as of December 31, 2023 and December 31, 2022, the related statements of operations, changes in stockholders’ equity and cash flows for the years then ended, the footnotes thereto, and the report of Marcum LLP, an independent registered public accounting firm, are filed herewith.

(2) Financial Schedules:

None. Financial statement schedules have been omitted because they are either not applicable or the required information is included in the financial statements or notes thereto.

(3) Exhibits:

The exhibits listed in the accompanying index to exhibits are filed with this Report or incorporated by reference into this Item 15(a)(3) as part of this Report.

(b) The following are exhibits to this Report and, if incorporated by reference, we have indicated the document previously filed with the SEC in which the exhibit was included.

Certain of the agreements filed as exhibits to this Report contain representations and warranties by the parties to the agreements that have been made solely for the benefit of such parties. These representations and warranties:

- may have been qualified by disclosures that were made to the other parties in connection with the negotiation of the agreements, which disclosures are not necessarily reflected in the agreements;
- may apply standards of materiality that differ from those of a reasonable investor; and
- were made only as of specified dates contained in the agreements and are subject to subsequent developments and changed circumstances.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date that these representations and warranties were made or at any other time. Investors should not rely on them as statements of fact.

Exhibit No.	Description of Exhibit
2.1	Contribution Agreement (filed as Exhibit 2.1 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).
2.2	Side Letter to Contribution Agreement (filed as Exhibit 2.2 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
3.1	Amended and Restated Certificate of Incorporation (filed as Exhibit 3.1 to Registrant's Current Report on Form 8-K, filed with the SEC on February 22, 2024 and incorporated by reference herein).
3.2	Certificate of Designation of Series A Convertible Preferred Stock, as currently in effect (filed as Exhibit 3.2 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).
3.3*	Certificate of Designation of Series C Convertible Preferred Stock.
3.4	Amended and Restated By-Laws (filed as Exhibit 3.2 to Registrant's Current Report on Form 8-K, filed with the SEC on February 22, 2024 and incorporated by reference herein).
4.1	Representative's Warrant (filed as Exhibit 4.1 to Registrant's Current Report on Form 8-K, filed with the SEC on February 22, 2024 and incorporated by reference herein).
4.2*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
4.4	Investor Promissory Note Issued by the Company (filed as Exhibit 4.6 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).
4.5	Side Letter to Amended and Restated Investor Promissory Note issued by the Company (filed as Exhibit 4.7 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 30, 2023 and incorporated by reference herein).
4.6	Second Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.6 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 30, 2023 and incorporated by reference herein).
4.7	Third Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.4 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
4.8	Side Letter to Second Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.5 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
4.9	Director Promissory Note Issued by the Company (filed as Exhibit 4.7 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).
4.10	Form of Senior Secured Convertible Promissory Note (April Bridge Financing; included in Exhibit 10.4) (filed as Exhibit 4.6 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on July 20, 2023 and incorporated by reference herein).
4.11	Form of Senior Secured Convertible Promissory Note (September Bridge Financing; included in Exhibit 10.6) (filed as Exhibit 4.8 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
4.12	Amendment No. 1 to Third Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.8 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
4.13	Side Letter to Third Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.9 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
4.14	Fourth Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.10 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
4.15	First Amendment to Senior Secured Convertible Note (April Bridge Financing) (filed as Exhibit 4.11 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 25, 2023 and incorporated by reference herein).

4.16	October Promissory Note Issued by the Company (AME Equities LLC) (filed as Exhibit 4.12 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
4.17	October Promissory Note Issued by the Company (Balmoral Financial Group LLC) (filed as Exhibit 4.13 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
4.18	October Promissory Note Issued by the Company (Camden Capital LLC) (filed as Exhibit 4.14 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
4.19	October Promissory Note Issued by the Company (MDB Merchants Park LLC) (filed as Exhibit 4.15 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
4.20	Second Amendment to Senior Secured Convertible Note (April Bridge Financing) (filed as Exhibit 4.16 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 25, 2023 and incorporated by reference herein).
4.21	Amended and Restated October Promissory Note Issued by the Company (AME Equities LLC) (filed as Exhibit 4.17 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on November 8, 2023 and incorporated by reference herein).
4.22	Amended and Restated October Promissory Note Issued by the Company (Balmoral Financial Group LLC) (filed as Exhibit 4.18 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on November 8, 2023 and incorporated by reference herein).
4.23	Amended and Restated October Promissory Note Issued by the Company (Camden Capital LLC) (filed as Exhibit 4.19 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on November 8, 2023 and incorporated by reference herein).
4.24	Amended and Restated October Promissory Note Issued by the Company (MDB Merchants Park LLC) (filed as Exhibit 4.20 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on November 8, 2023 and incorporated by reference herein).
4.25	Third Amendment to Senior Secured Convertible Note (April Bridge Financing) (filed as Exhibit 4.21 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).
4.26	Side Letter to Fourth Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.22 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).
4.27	Fifth Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.23 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).
4.28	Second Amended and Restated October Promissory Note Issued by the Company (AME Equities LLC) (filed as Exhibit 4.24 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).
4.29	Second Amended and Restated October Promissory Note Issued by the Company (Balmoral Financial Group LLC) (filed as Exhibit 4.25 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).
4.30	Second Amended and Restated October Promissory Note Issued by the Company (Camden Capital LLC) (filed as Exhibit 4.26 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).
4.31	Second Amended and Restated October Promissory Note Issued by the Company (MDB Merchants Park LLC) (filed as Exhibit 4.27 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).
4.32	Stock Issuance Agreement (Benuvia License Agreement) (filed as Exhibit 4.28 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).
4.33	Amendment No. 1 to Director Promissory Note Issued by the Company (filed as Exhibit 4.29 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).

4.34	Side Letter to Fifth Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.30 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 30, 2024 and incorporated by reference herein).
4.35	Sixth Amended and Restated Investor Promissory Note Issued by the Company (filed as Exhibit 4.31 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 30, 2024 and incorporated by reference herein).
4.36	Fourth Amendment to Senior Secured Convertible Note (April Bridge Financing) (filed as Exhibit 4.32 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on February 12, 2024 and incorporated by reference herein).
4.37	First Amendment to Senior Secured Convertible Note (September Bridge Financing) (filed as Exhibit 4.33 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on February 12, 2024 and incorporated by reference herein).
4.38	Stock Rescission Agreement (filed as Exhibit 4.34 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on February 12, 2024 and incorporated by reference herein).
10.1+	Chromocell Therapeutics Corporation 2023 Equity Incentive Plan (filed as Exhibit 10.1 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).
10.2+	Amended and Restated Employment Agreement (Christian Kopfli) (filed as Exhibit 10.2 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
10.3+	Amended and Restated Consultant Agreement (Camden Capital LLC) (filed as Exhibit 10.3 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 30, 2023 and incorporated by reference herein).
10.4	Securities Purchase Agreement (April Bridge Financing) (filed as Exhibit 10.4 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on July 20, 2023 and incorporated by reference herein).
10.5	Security Agreement (April Bridge Financing) (filed as Exhibit 10.5 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on July 20, 2023 and incorporated by reference herein).
10.6	Securities Purchase Agreement (September Bridge Financing) (filed as Exhibit 10.6 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
10.7	Security Agreement (September Bridge Financing) (filed as Exhibit 10.7 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
10.8	Subordination and Intercreditor Agreement (September Bridge Financing) (filed as Exhibit 10.8 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on September 1, 2023 and incorporated by reference herein).
10.9	Securities Purchase Agreement (Series B Preferred Stock) (filed as Exhibit 10.9 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
10.10	Registration Rights Agreement (Series B Preferred Stock) (filed as Exhibit 10.10 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on October 16, 2023 and incorporated by reference herein).
10.11+	Employment Agreement (Eric Lang) (filed as Exhibit 10.7 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 30, 2023 and incorporated by reference herein).
10.12+	First Amendment to Chromocell Therapeutics Corporation 2023 Equity Incentive Plan (filed as Exhibit 4.4 to Registrant's Registration Statement on Form S-8, filed with the SEC on April 15, 2024 and incorporated by reference herein).
10.13	Side Letter re Securities Purchase Agreement (Standby Shares) (filed as Exhibit 10.13 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).
10.14+	Benuvia License Agreement (filed as Exhibit 10.14 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 16, 2024 and incorporated by reference herein).

10.15	Consulting Agreement (Francis Knuettel II) (filed as Exhibit 10.3 to Registrant's Registration Statement on Form S-1/A, filed with the SEC on January 20, 2023 and incorporated by reference herein).
10.16	Form of Restricted Stock Unit Agreement under the Chromocell Therapeutics Corporation 2023 Equity Incentive Plan (filed as Exhibit 4.5 to Registrant's Registration Statement on Form S-8, filed with the SEC on April 15, 2024 and incorporated by reference herein).
10.17	Form of Stock Option Agreement under the Chromocell Therapeutics Corporation 2023 Equity Incentive Plan (filed as Exhibit 4.6 to Registrant's Registration Statement on Form S-8, filed with the SEC on April 15, 2024 and incorporated by reference herein).
19.1*	Insider Trading Policy.
23.1*	Consent of Marcum LLP.
31.1#*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2#*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1+*	Compensation Recovery Policy
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Schema
101.CAL	XBRL Taxonomy Calculation Linkbase
101.DEF	XBRL Taxonomy Definition Linkbase
101.LAB	XBRL Taxonomy Label Linkbase
101.PRE	XBRL Taxonomy Presentation Linkbase
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

+ Indicates management contract or compensatory plan.

The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to be furnished with this Report and will not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Chromocell Therapeutics Corporation

Date: April 16, 2024

By: /s/ Francis Knuettel II
Name: Francis Knuettel II
Title: Chief Executive Officer, Chief Financial Officer, Treasurer and Secretary
(Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: April 16, 2024 By: /s/ Francis Knuettel II
Francis Knuettel II
Chief Executive Officer, Chief Financial Officer, Treasurer and Secretary

Date: April 16, 2024 By: /s/ Ezra Friedberg
Ezra Friedberg
Director

Date: April 16, 2024 By: /s/ Todd Davis
Todd Davis
Director

Date: April 16, 2024 By: /s/ Richard Malamut
Richard Malamut
Director

Date: April 16, 2024 By: /s/ Chia-Lin Simmons
Chia-Lin Simmons
Director

CHROMOCELL THERAPEUTICS CORPORATION

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Chromocell Therapeutics Corporation
Freehold, New Jersey

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Chromocell Therapeutics Corporation (the "Company") as of December 31, 2023 and 2022, the related statements of operations, changes in stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Emphasis of Matter

As discussed in Note 4, the financial statements for the period from January 1, 2022 to August 10, 2022 have been prepared on a "carve-out" basis from the financial statements of Chromocell Holdings to reflect the assets, liabilities, revenues and expenses of Chromocell Therapeutics Corporation as well as allocations deemed reasonable by management to present the results of operations, financial position and cash flows of Chromocell Therapeutics Corporation on a standalone basis and may not reflect Chromocell Therapeutics Corporation results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Our Opinion is not modified with respect to this matter.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2021.

Houston, Texas
April 16, 2024

CHROMOCELL THERAPEUTICS CORPORATION
BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash	$ 96,391	$ 55,074
TOTAL CURRENT ASSETS	96,391	55,074
TOTAL ASSETS	$ 96,391	$ 55,074
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 4,620,925	$ 2,993,920
Accrued compensation	645,947	221,875
Bridge loan, net of debt discount	316,324	435,630
Loan payable, net of debt discount	202,279	—
Loan payable - related party, net of debt discount	750,082	104,800
Due to Chromocell Corporation	5,386	5,386
TOTAL CURRENT LIABILITIES	6,540,943	3,761,611
TOTAL LIABILITIES	6,540,943	3,761,611
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT		
Preferred stock Series A, $0.001 par value, 700,000 shares authorized, 600,000 and 600,000 shares issued and outstanding as of December 31, 2023 and 2022, respectively	60	60
Preferred stock series B, $0.001 par value, 5,000 shares authorized, 0 and 0 shares issued and outstanding as of December 31, 2023 and 2022, respectively	—	—
Preferred stock series C, $0.001 par value, 5,000 shares authorized, 0 and 0 shares issued and outstanding as of December 31, 2023 and 2022, respectively	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 3,914,338 and 1,111,112 shares issued and outstanding as of December 31, 2023 and 2022, respectively	391	111
Additional paid in capital	7,074,646	2,432,148
Accumulated / parent's net deficit	(13,519,649)	(6,138,856)
TOTAL STOCKHOLDERS' DEFICIT	(6,444,552)	(3,706,537)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 96,391	$ 55,074

The accompanying notes are an integral part to these financial statements.

CHROMOCELL THERAPEUTICS CORPORATION
STATEMENTS OF OPERATIONS

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022
OPERATING EXPENSES		
General and administrative expenses	$ 2,738,948	$ 1,098,848
Research and development	2,579,418	391,730
Professional fees	1,543,918	827,581
Total operating expenses	6,862,284	2,318,159
NET LOSS FROM OPERATIONS	(6,862,284)	(2,318,159)
OTHER (EXPENSE) INCOME		
Interest expense	(518,509)	(140,430)
Total other (expense) income	(518,509)	(140,430)
Net loss before provision for income taxes	(7,380,793)	(2,458,589)
Provision for income taxes	—	—
NET LOSS	$ (7,380,793)	$ (2,458,589)
Net loss per common share - basic and diluted	$ 5,78)	$ 5,65)
Weighted average number of common shares outstanding during the year - basic and diluted	1,276,543	435,312

The accompanying notes are an integral part to these financial statements.

CHROMOCELL THERAPEUTICS CORPORATION
STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE YEAR ENDED DECEMBER 31, 2023 and 2022

	Common Shares	Par	Preferred Shares	Preferred Shares Par	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance, December 31, 2021	—	$ —	—	$ —	$ —	$ (3,680,267)	$ (3,680,267)
Fair value of shares issued in contribution agreement	10,000,000	111	600,000	60	1,889,400	—	1,900,000
Net contributions from Chromocell Corporation	—	—	—	—	422,173	—	422,173
Stock-based compensation	—	—	—	—	110,146	—	110,146
Net loss	—	—	—	—	—	(2,458,589)	(2,458,589)
Balance, December 31, 2022	10,000,000	1	600,000	60	2,421,719	(6,138,856)	(3,706,537)
Stock-based compensation	—	—	—	—	1,733,233	—	1,733,233
Shares issued for extension of bridge loan	18,892	2	—	—	428,398	—	428,400
Shares issued for license	384,226	38	—	—	2,225,695	—	2,225,733
Shares issued for cash	2,533,853	253	—	—	255,159	—	255,412
Shares forfeited	(133,745)	(13)	—	—	13	—	—
Net loss	—	—	—	—	—	(7,380,793)	(7,380,793)
Balance December 31, 2023	3,914,338	$ 391	600,000	$ 60	$ 7,074,646	$ (13,519,649)	$ (6,444,552)

The accompanying notes are an integral part to these financial statements.

CHROMOCELL THERAPEUTICS CORPORATION
STATEMENTS OF CASH FLOWS

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,380,793)	$ (2,458,589)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of debt discount	188,119	140,430
Issuance cost from shares issued on extension of bridge loan	201,600	—
Stock-based compensation	1,733,233	110,146
Shares issued for license	2,225,733	—
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	1,627,005	413,603
Accrued compensation	424,072	221,875
Due to parent	—	5,386
Net Cash Used In Operating Activities	(981,031)	(1,567,149)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from loan payable, net of debt discount	201,008	—
Proceeds from loan payable - related party, net of debt discount	565,928	100,000
Proceeds from bridge loan, net of debt discount	—	300,000
Shares issued for cash	255,412	—
Net contribution from Chromocell Corporation	—	422,173
Advance from Chromocell Corporation	—	800,050
Net Cash Provided By Financing Activities	1,022,348	1,622,223
NET INCREASE (DECREASE) IN CASH	41,317	55,074
CASH AT BEGINNING OF PERIOD	55,074	—
CASH AT END OF PERIOD	$ 96,391	$ 55,074
Supplemental cash flow information:		
Cash paid for income taxes	$ —	$ —
Cash paid for interest expense	$ —	$ —
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Fair value of shares issued in contribution agreement	$ —	$ 1,900,000
Debt discount from shares issued on extension of bridge loan	$ 428,400	$ —
Shares forfeited	$ 13	$ —

The accompanying notes are an integral part to these financial statements.

CHROMOCELL THERAPEUTICS CORPORATION
NOTES TO FINANCIAL STATEMENTS

NOTE 1 – ORGANIZATION AND NATURE OF BUSINESS

Company Background

Chromocell Therapeutics Corporation ("Chromocell" or the "Company") was incorporated in the State of Delaware on March 19, 2021. On August 10, 2022, the Company entered into that certain Contribution Agreement (the "Contribution Agreement") with Chromocell Corporation, a Delaware corporation ("Chromocell Holdings"), pursuant to which, effective July 12, 2022 (the "Contribution Date"), Chromocell Holdings contributed all assets and liabilities related to Chromocell Holdings' historical therapeutic business, including all patents, pre-clinical and Phase I study results and data, and trade secrets related to the CC8464 compound to the Company. (See Note 4)

The Company is a development stage life sciences company which improves consumer products and patient lives through breakthrough science and technologies. The Company is focused on the discovery and development of therapeutics through the use of pioneering Chromovert® technology. Chromovert technology enables the Company to use rare cells ideally suited for effective high-throughput screening. The Company's therapeutics pipeline is currently focused on analgesics and rare diseases, where Chromovert technology has proven highly effective in the rapid identification of potential new drug candidates.

The Company has a limited operating history and has not generated revenue from its intended operations. The Company's business and operations are sensitive to general business and economic conditions in the U.S. and worldwide along with local, state, and federal governmental policy decisions. A host of factors beyond the Company's control could cause fluctuations in these conditions. Adverse conditions may include changes in the biotechnology regulatory environment, technological advances that render our technologies obsolete, availability of resources for clinical trials, acceptance of technologies into the medical community, and competition from larger, more well-funded companies.

On January 30, 2020, the World Health Organization declared the COVID-19 novel coronavirus outbreak a "Public Health Emergency of International Concern" and on March 10, 2020, declared it to be a pandemic. Actions taken around the world to help mitigate the spread of the coronavirus include restrictions on travel, and quarantines in certain areas, and forced closures for certain types of public places and businesses. The COVID-19 coronavirus and actions taken to mitigate it have had and are expected to continue to have an adverse impact on the economies and financial markets of many countries, including the geographical area in which the Company operates. On May 11, 2023, the United States government declared an end to the COVID-19 pandemic, but it is reasonably possible that future capital raising efforts and additional development of our technologies may still be negatively affected.

On February 21, 2024, the Company completed the initial public offering of its Common Stock (the "IPO") and issued and sold 1,100,000 shares of Common Stock at a price to the public of $6.00 per share. The aggregate net proceeds from the IPO were approximately $5.7 million after deducting underwriting discounts and commissions and offering expenses.

NOTE 2 – GOING CONCERN ANALYSIS

Management Plans

During the year ended December 31, 2023, the Company had a net loss of $ 7,380,793 and cash of $96,391 at December 31, 2023. These factors indicate substantial doubt about the Company's ability to continue as a going concern for the twelve months following the issuance of these financial statements, but these doubts are alleviated by the additional funds raised subsequent to the period from the Company's IPO. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern.

The financial statements included in this report do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the matters discussed herein. While the Company believes in the viability of our strategy to generate sufficient revenue, control costs, and raise additional funds, when necessary, there can be no assurances to that effect. The Company's ability to continue as a going concern is dependent upon the ability to implement the business plan, generate sufficient revenues and to control operating expenses.

Liquidity and Capital Resources

At December 31, 2023, the Company had $ 0.1 million in cash and cash equivalents and a working capital deficit of approximately $ 6.4 million, compared to approximately $0.1 million in cash and cash equivalents and a working capital deficit of approximately $ 3.7 million at December 31, 2022.

Based on the Company's current projections, management believes there is substantial doubt about its ability to continue to operate as a going concern and fund its operations through at least the next twelve months following the issuance of these financial statements. While the Company will continue to invest in its business and the development of CC8464 and CT2000, and potentially other molecules, and it is unlikely that the Company will generate product or licensing revenue during the next twelve months. Subsequent to the period, the Company completed its initial public offering, raising $5.7 million, and the Company may need to raise additional funds through either strategic partnerships or the capital markets. However, there is no assurance that the Company will be able to raise such additional funds on acceptable terms, if at all. If the Company raises additional funds by issuing securities, existing stockholders may be diluted.

If adequate funds are not available and expenditures exceed the Company's current expectations, the Company may be required to curtail its operations or other business activities or obtain funds through arrangements with strategic partners or others that may require the Company to relinquish rights to certain technologies or potential markets.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

Prior to the execution of the Contribution Agreement between Chromocell and Chromocell Holdings (see Note 4), Chromocell did not constitute a separate legal entity or group and as such, stand-alone financial statements were not previously prepared for the Company. As a result, carve-out financial statements for Chromocell were prepared for the year ended December 31, 2022, which include all of Chromocell's operations which have been conducted within Chromocell Holdings, which also has other activities. These financial statements have been prepared on a stand-alone basis derived from the financial statements and related accounting records of Chromocell Holdings. The accompanying carve-out financial statements present the historical financial position, results of operations, changes in net assets and cash flows of the Company as it was historically conducted, as more fully described below in Note 4. The financial information in these financial statements does not necessarily include all the expenses that would have been incurred had the Company operated as a separate stand-alone entity and may not reflect results of operations, financial position and cash flows had the Company been a stand-alone company during the year ended September 30, 2023.

With the execution of the Contribution Agreement on August 12, 2022, effective for the reporting period ended December 31, 2022 and all future reporting periods, the financial statements reflect Chromocell as a stand-alone entity.

For all periods, the Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates made by management include, but are not limited to, estimating the useful lives of patent assets, realization of long-lived assets, valuation of deferred income taxes, unrealized tax positions and business combination accounting.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of December 31, 2023 and December 31, 2022, the Company did not have any cash equivalents. As of December 31, 2023 and December 31, 2022, the Company did not have any deposits in excess of Federally insured limits.

Research and Development

We incur research and development costs during the process of researching and developing our technologies and future offerings. We expense these costs as incurred unless such costs qualify for capitalization under applicable guidance. The Company reviews acquired R&D and licenses to determine if they should be capitalized or expensed under U.S. GAAP standards.

Below is a disaggregation of R&D expenses:

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022
Consultant	$ 68,900	$ 86,802
Lab Gas	—	13,871
Lab Cell Storage	48,572	62,197
Chemistry Manufacturing and Controls (“CMC”)	—	3,800
IP Services	2,461,946	225,060
Total	$ 2,579,418	$ 391,730

Fair Value Measurements and Fair Value of Financial Instruments

The Company adopted FASB ASC Topic 820, Fair Value Measurements (“ASC Topic 820”). ASC Topic 820 clarifies the definition of fair value, prescribes methods for measuring fair value, and establishes a fair value hierarchy to classify the inputs used in measuring fair value as follows:

- Level 1 Inputs are unadjusted quoted prices in active markets for identical assets or liabilities available at the measurement date.
- Level 2 Inputs are unadjusted quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, inputs other than quoted prices that are observable, and inputs derived from or corroborated by observable market data.
- Level 3 Inputs are unobservable inputs which reflect the reporting entity’s own assumptions on what assumptions the market participants would use in pricing the asset or liability based on the best available information.

The Company did not identify any assets or liabilities that are required to be presented on the balance sheets at fair value in accordance with ASC Topic 820.

Due to the short-term nature of all financial assets and liabilities, their carrying value approximates their fair value as of the balance sheet dates.

Stock-Based Compensation

The Company accounts for stock-based compensation costs under the provisions of ASC 718, Compensation—Stock Compensation, which requires the measurement and recognition of compensation expense related to the fair value of stock-based compensation awards that are ultimately expected to vest. Stock-based compensation expense recognized includes the compensation cost for all stock-based payments granted to employees, officers, and directors based on the grant date fair value estimated in accordance with the provisions of ASC 718. ASC 718 is also applied to awards modified, repurchased, or cancelled during the periods reported. Stock-based compensation is recognized as expense over the employee's requisite vesting period and over the nonemployee's period of providing goods or services. Pursuant to ASC 718, the Company can elect to either recognize the expenses on a straight-line or graded basis and has elected to do so under the straight-line basis.

Basic and Diluted Net Loss per Common Share

Basic loss per common share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for each period. Diluted loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding plus the dilutive effect of shares issuable through the common stock equivalents. The weighted-average number of common shares outstanding excludes common stock equivalents because their inclusion would be anti-dilutive. As of December 31, 2023, 197,560 stock options were excluded from dilutive earnings per share as their effects were anti-dilutive.

Income Taxes

The Company accounts for income taxes pursuant to the provision of ASC 740 "Accounting for Income Taxes," which requires, among other things, an asset and liability approach to calculating deferred income taxes. The asset and liability approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. A valuation allowance is provided to offset any net deferred tax assets for which management believes it is more likely than not that the net deferred asset will not be realized.

The Company follows the provision of the ASC 740 related to Accounting for Uncertain Income Tax Position. When tax returns are filed, it is more likely than not that some positions taken would be sustained upon examination by the taxing authorities, while others are subject to uncertainty about the merits of the position taken or the amount of the position that would be ultimately sustained. In accordance with the guidance of ASC 740-10, the benefit of a tax position is recognized in the financial statements in the period during which, based on all available evidence, management believes it is most likely that not that the position will be sustained upon examination, including the resolution of appeals or litigation processes, if any. Tax positions taken are not offset or aggregated with other positions.

Tax positions that meet the more-likely-than-not recognition threshold are measured as the largest amount of tax benefit that is more than 50% likely of being realized upon settlement with the applicable taxing authority. The portion of the benefits associated with tax positions taken that exceeds the amount measured as described above should be reflected as a liability for uncertain tax benefits in the accompanying balance sheet along with any associated interest and penalties that would be payable to the taxing authorities upon examination. The Company believes its tax positions will more likely than not be upheld upon examination. As such, the Company has not recorded a liability for uncertain tax benefits.

The federal and state income tax returns of the Company are subject to examination by the Internal Revenue Service and state taxing authorities, generally for three years after they were filed. The Company is in the process of filing the tax returns for the 2023 year. After review of the prior year financial statements and the results of operations through December 31, 2023, the Company has recorded a full valuation allowance on its deferred tax asset.

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments, which was codified in Accounting Standards Codification ("ASC") 326, Financial Instruments — Credit Losses ("ASC 326"). The standard changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. Because the Company is a smaller reporting company based on the most recent determination as of November 15, 2019, ASC 326 became effective for the Company for fiscal years beginning after December 15, 2022. As such, the Company adopted ASC 326 effective January 1, 2023, utilizing the modified retrospective transition method. Upon adoption, the Company updated its impairment model to utilize a forward-looking current expected credit losses ("CECL") model in place of the incurred loss methodology for financial instruments measured at amortized cost, primarily including its accounts receivable and contract asset. In relation to available-for-sale ("AFS") debt securities, the guidance eliminates the concept of "other-than-temporary" impairment, and instead focuses on determining whether any impairment is a result of a credit loss or other factors. The adoption of ASC 326 did not have a material impact on our financial statements as of the adoption date.

In August 2020, the FASB issued ASU 2020-06, which simplifies the guidance on the issuer's accounting for convertible debt instruments by removing the separation models for convertible debt with a cash conversion feature and convertible instruments with a beneficial conversion feature. As a result, entities will not separately present in equity an embedded conversion feature in such debt and will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. The elimination of these models will reduce reported interest expense and increase reported net income for entities that have issued a convertible instrument that is within the scope of ASU 2020-06. Also, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and treasury stock method will be no longer available. ASU 2020-06 is applicable for fiscal years beginning after December 15, 2022, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The adoption of this ASU did not have a material effect on the Company's financial statements.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires disaggregated information about a reporting entity's effective tax rate reconciliation, as well as information related to income taxes paid to enhance the transparency and decision usefulness of income tax disclosures. This ASU will be effective for the annual period ending December 31, 2025. The Company is currently evaluating the timing and impacts of adoption of this ASU.

Subsequent Events

The Company has evaluated all transactions through the date the financial statements were issued for subsequent event disclosure consideration.

NOTE 4 – CARVE-OUT CRITERIA AND ASSUMPTIONS

The carve-out statements of operations, as set forth above for the year ended December 31, 2022 and which was the subject of the statement of operations contained herein, reflect direct revenues and expenses and allocations of indirect expenses related to certain support functions that were provided on a centralized basis by Chromocell Holdings. These expenses, assets, and liabilities were allocated to the Company on the basis of direct usage when identifiable, with others allocated based on relevant data criteria.

- Employment related expenses – allocated all Chromocell direct salaries and an allocation of headquarters salaries based on headcounts.
- General and administrative expenses and Professional fees – allocated all direct Chromocell related expenses and corporate expense have been allocated to reflect the utilization of those corporate services by the Company.
- Research and development expenses – all Research and development expenses are direct Chromocell expenses.
- Rent and related expenses and security deposits – applied a ratio based on floor space used by Chromocell.
- Long lived assets – long lived assets are owned by Chromocell Holdings Inc and under shared use by its components including the Company. Operating expenses are allocated that reflect the usage of the long-lived asset by the Company.
- Accounts payable and accrued expenses – allocated all direct Chromocell liabilities and an allocation corporate expense reflecting the utilization of those corporate services by the Company.
- PPP loan and PPP loan forgiveness – allocated to reflect the utilization of the proceeds by the Company.
- Bridge loan – the bridge loan was fully allocated to the Company. (See Note 6)

Chromocell Holdings uses a centralized approach to cash management of its operations. Any cash excess over comprehensive income earned by the Company were transferred to Chromocell Holdings through "net parent investment." Accordingly, none of the Chromocell Holdings cash and cash equivalents, have been assigned to the Company in the carve-out combined financial statements.

As these carve-out financial statements present a portion of the business of Chromocell Holdings, which does not constitute a separate legal entity for the purposes of carve-out financial statements, the net assets of the Chromocell Holdings have been presented as parent's net deficit. Except for the PPP loan, Chromocell Holdings third-party bank loans, related party loans and the related interest expense have not been included in the carve-out financial statements for any of the periods presented. Chromocell is not the legal obligor on those loans, and they were not directly attributable to the Chromocell operations.

As the lease is held by Chromocell Holdings, the Company does not have the right to control the use of the space being leased and only shares the space. As such, there is no lease liability or right of use asset recorded for Chromocell.

Management believes the assumptions underlying the carve-out, including the assumptions regarding allocation of expenses, are reasonable.

For the year ended December 31, 2023, the financial statements reflect Chromocell as a stand-alone entity.

Contribution Agreement

On August 10, 2022, the Company and Chromocell Holdings Corporation ("Chromocell Holdings") entered into the Contribution Agreement effecting (1) the contribution by Chromocell Holdings to the Company of assets related to Chromocell Holding's Therapeutics Business, including all intellectual property related to Chromocell Holding's NaV1.7 program and its clinical-stage CC8464 lead compound, (2) assumption by the Company of direct–liabilities related to Chromocell Holding's historical Therapeutics Business in the amount of $1,556,323 as well as a cash payment by the Company to Chromocell Holdings of $597,038 and (3) the issuance by the Company to Chromocell Holdings of 10,000,000 shares of its common stock and 600,000 shares of its Series A Convertible Preferred Stock.

As part of the contribution agreement, Chromocell Holdings transferred to the Company assets related to Chromocell Holding's Therapeutics Business, including all the patents and intellectual property related to Chromocell Holding's NaV1.7 program and its clinical-stage CC8464 lead compound.

The Company analyzed the transaction for common control pursuant to ASC 805-50. While the term "common control" is not defined, there are examples in the Transactions between Entities under Common Control Subsection that, among others, indicates that "an entity [that] charters a newly formed entity and then transfers some or all of its assets to the newly chartered entity" is an example of a transaction involving common control, yielding recordation of assets at the transferors' historical cost basis. This directly mirrors the terms underlying the Contribution Agreement whereby Holdings established the Company as wholly owned subsidiary and transferred the Intangibles in return to 100% of the stock of the Company. Further, Staff Accounting Bulletin ("SAB") Topic 5G dictates that "transfers of nonmonetary assets to a company by its promoters or shareholders in exchange for stock prior to or at the time of the company's initial public offering normally should be recorded at the transferors' historical cost basis determined under GAAP." As a result, pursuant to ASC 805-50 and SAB Topic 5G, the Company recorded the net assets acquired at historical value when the Contribution Agreement was executed.

All of the assets, liabilities and results of operations of the Company as of and for the periods prior to the Contribution Date were identified based on the assets contributed to the Company from Chromocell Holdings. Management believes the assumptions underlying the Company's carve-out financial statements are reasonable. Nevertheless, the financial statements may not include all of the actual expenses that would have been incurred had the Company operated as a standalone company during the periods presented, and may not reflect the Company's results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Actual costs that would have been incurred if the Company had operated as a standalone company would depend on multiple factors, including organizational structure and strategic decisions made in various areas, including information technology and infrastructure.

NOTE 5 – RELATED PARTY TRANSACTIONS

Employment Agreement

The Company entered into an employment agreement with Christian Kopfli, dated January 10, 2023. Pursuant to such agreement, Mr. Kopfli agreed to serve as the Company's Chief Executive Officer and Vice-Chairman of its Board of Directors (the "Board") in consideration for an annualized salary of $275,000, payable in cash at the rate of $5,000 per month (a minimum of $1,125 per week), with the remainder accrued and paid as of the earliest of a sale or liquidation of the Company, the Company's bankruptcy or three days after the approval by the Board of a funded budget with appropriately established milestones subsequent to the effective date of a Form S-1 registration statement ("Post-registration Approval"). Mr. Kopfli also agreed, as of Post-registration Approval, to resign as Chief Executive Officer of Chromocell Corporation although he may continue service on the Board of Directors of Chromocell Corporation, including as its Board Chairperson. The employment agreement provides that Mr. Kopfli receive an option to acquire 22,223 shares of the Company's common stock, vesting quarterly over 10 quarters beginning on October 1, 2022. This option shall have an exercise price equal to the fair market value of the Company's common stock on the date of grant and shall expire on the 10th anniversary of the date of grant. The option was awarded as of January 10, 2023. The employment agreement contemplates an annual bonus, as determined by the Board. The target bonus is 50% of Mr. Kopfli's annualized salary and will be based on achievement of performance goals and objectives agreed to by Mr. Kopfli and the Board in January of each year. The Board may increase the bonus in recognition of performance in excess of the performance objectives. Any bonus shall only be paid if Mr. Kopfli remains employed on the date of payment, which will be no later than March 15 of the year following the year to which the bonus relates. Any bonus for 2022 is payable solely at the Board's discretion.

Pursuant to Mr. Kopfli's employment agreement, in the event he is involuntarily terminated by the Company other than for "Cause" or if he resigns for "Good Reason," he is entitled to receive (i) six months of salary at the same rate existing immediately prior to his termination, (ii) his target bonus, if performance goals and objectives have been established for the year and prorated for the period of service, and (iii) six months of additional vesting credit with respect to any outstanding time-based equity awards. "Cause" and "Good Reason" are each defined in the employment agreement.

Finally, Mr. Kopfli agrees to certain non-solicitation and non-competition provisions for a period of 12 months following termination and to certain confidentiality obligations. Additional terms and conditions are set forth in the employment agreement.

On July 28, 2023, the Company amended and restated Mr. Kopfli's employment agreement whereby Mr. Kopfli's title changed to Vice Chairman and Chief Strategy Officer. Other terms and conditions of the amended and restated employment agreement remain the same.

On November 27, 2023, Mr. Kopfli was removed from the Company's Board by the stockholders having a majority of the number of votes necessary to take such action. Mr. Kopfli was then terminated from his position as Vice Chairman and Chief Strategy Officer by the Company for "Cause", as defined in Mr. Kopfli's employment agreement, effective December 1, 2023.

On February 14, 2024, the Board received a demand letter from an attorney representing Chromocell Holdings and Mr. Kopfli. Mr. Kopfli alleges an improper termination for “cause” and seeks monetary damages in connection therewith in the amount of $479,169. Of the $479,169 asserted by Mr. Kopfli, as of December 31, 2023, the Company has accrued $363,091 in compensation expenses associated with Mr. Kopfli’s prior employment with the Company. To the extent Mr. Kopfli is successful in his assertions, the Company will pay any amounts owed thereunder from future working capital reserves; however, the Company believe the assertions made by Mr. Kopfli are without merit and intend to vigorously defend the matter.

Consultant Agreement

The Company entered into a Consultant Agreement with Camden Capital LLC, dated January 10, 2023. This consultant agreement replaces an agreement with Mr. Francis Knuettel II dated June 2, 2022, and pursuant to the agreement, Camden Capital LLC agreed to provide the services of Mr. Knuettel, who is serving as the Company’s Chief Financial and Strategy Officer, Treasurer and Secretary.

Under the consultant agreement with Camden Capital LLC, the Company accrued a consulting fee for the period June 6, 2022 through August 31, 2022 of $10,000 per month and effective September 1, 2022, began to accrue a consulting fee of $20,000 per month, payable in cash at the rate of $5,000 per month (a minimum of $1,125 per week), with the remainder accrued. The expenses for these were recognized in the periods that they occurred. All accrued consulting fees are payable as of the earliest of a sale or liquidation of the Company, the Company’s bankruptcy or three days after Post-registration Approval. The consulting agreement provides for the following equity awards to Camden Capital LLC: (i) an option, awarded as of January 10, 2023, to acquire 22,223 shares of the Company’s common stock, vesting quarterly over 10 quarters beginning on October 1, 2022 , with the option having an exercise price equal to the fair market value of the Company’s common stock on the date of grant and expiring on the 10th anniversary of the date of grant; (ii) an option, awarded as of January 10, 2023, to acquire 2,778 shares of the Company’s common stock, vesting 100% upon the sooner of the sale of the Company or Post-registration Approval, with the option having an exercise price equal to the fair market value of the Company’s common stock on the date of grant and expiring on the 10th anniversary of the date of grant; and (iii) an RSU, awarded as of January 10, 2023, of 16,667 shares of the Company’s common stock, vesting 100% on the day after the first trading window that opens after Post-registration Approval. The Company began recognizing the vesting expense for the options during the year ended December 31, 2022.

The consultant agreement contemplates an additional consulting fee, as determined by the Board. The potential additional consulting fee is 50% of the annualized consulting fee and will be based on achievement of performance goals and objectives established by the Board in concert with Mr. Knuettel in January of each year. The Board may increase the potential additional consulting fee in recognition of performance in excess of the performance objectives. Any amount shall only be paid if Camden Capital LLC continues to provide consulting services to the Company as of the date of payment, which will be no later than March 15 of the year following the year to which the additional consulting fee relates. Any additional consulting fee for 2022 is payable solely at the Board’s discretion.

Pursuant to the consultant agreement, in the event the relationship with Camden Capital LLC is involuntarily terminated by the Company other than for “Cause” or if Camden Capital LLC terminates the relationship for “Good Reason,” Camden Capital LLC is entitled to receive (i) six months of consulting fees at the same rate existing immediately prior to termination, (ii) a potential additional consulting fee, if performance goals and objectives have been established for the year and prorated for the period of service, and (iii) six months of additional vesting credit with respect to any outstanding time-based equity awards. “Cause” and “Good Reason” are each defined in the consulting agreement.

Finally, Camden Capital LLC and Mr. Knuettel agree to certain non-solicitation and non-competition provisions for a period of 12 months following termination of the relationship and to certain confidentiality obligations. Additional terms and conditions are set forth in the consulting agreement.

Director Note

On December 6, 2022, the Company and Mr. Todd Davis, one of the Company’s directors, entered into the Director Note for $175,000. The Director Note has an original issuance discount of $75,000, and matures on December 31, 2023, or, if earlier to occur, upon the closing of an underwritten offering of securities resulting in at least $15 million in gross proceeds.

April and September Bridge Financings

On April 17, 2023 and September 1, 2023, the Company entered into bridge notes, the investors in which were almost entirely existing investors. Related party investors in the April Bridge Financing include Chromocell Holdings, Boswell Prayer Ltd., Motif Pharmaceuticals Ltd, Aperture Healthcare Ventures Ltd., MDB Merchants Park LLC, Balmoral Financial Group LLC and AME EQUITIES LLC (each a related party based on share ownership in excess of 5% or resulting from a principal at one of the entities being on the Company's board of directors). All of these investors, except Chromocell Holdings, also participated in the September Bridge Financing.

Due to Chromocell Corporation

As of December 31, 2023, the Company had a $ 5,386 liability due to Chromocell Corporation, a Delaware corporation ("Chromocell Holdings"), from which the Company was spun out in August 2022. This amount is comprised of expenses paid by the parent to be reimbursed by the Company. No interest is incurred on these amounts.

Side Letter to the Contribution Agreement and Issuance of Series C Convertible Redeemable Preferred Stock

On August 2, 2023, the Company entered into a side letter to the Contribution Agreement (the "Holdings Side Letter") with Chromocell Holdings. Pursuant to the side letter, upon closing of the Company's IPO: (a) Chromocell Holdings re-assumed all $1.6 million in direct liabilities previously assumed by the Company in accordance with the Contribution Agreement, (b) Chromocell Holdings waived the Company's obligations to make a cash payment in the amount of $0.6 million to Chromocell Holdings, and (c) in consideration thereof, the Company issued to Chromocell Holdings 2,600 shares of Series C Convertible Redeemable Preferred Stock of the Company, par value of $0.0001 per share (the "Series C Preferred Stock").

The Series C Preferred Stock has a liquidation preference of $ 1,000 per share. Holders of the Series C Preferred Stock are not entitled to dividends, have no voting rights other than as required by law, and the shares of Series C Preferred Stock are convertible into shares of Common Stock. Following the IPO, at the holder's option, are convertible into shares of Common Stock automatically if, the trading price of the Common Stock exceeds certain thresholds, and are redeemable by the Company for cash.

NOTE 6 – NOTES PAYABLE

Investor Note

On February 4, 2022, the Company entered into a note payable for $ 450,000 (the "Investor Note") with a third party. This Investor Note had an original issuance discount of $150,000, representing an implicit interest rate of 50%, a maturity date of February 3, 2023, and accrues no interest beyond the original issuance discount. As of December 31, 2023, the debt discount was fully amortized. There was $14,370 and $135,630, respectively, in amortization of debt discount included in interest expense on the statement of operations for the years ended December 31, 2023 and 2022.

On February 27, 2023, the Investor Note agreement was amended. The maturity date was extended from its original due date of February 3, 2023 to May 15, 2023, in return for the Company agreeing to pay 2% per month in accrued interest and the third party agreeing to settle its outstanding debt, including accrued interests in shares of common stock at the IPO. Accrued interest and related interest expense totaled $98,056 for the years ended December 31, 2023, compared to $0 for year ended December 31, 2022.

On June 23, 2023, the Company entered into a side letter with the holder of the Investor Note pursuant to which the Company (i) amended and restated the Investor Note to extend the maturity date to August 15, 2023 and (ii) in consideration therefor, issued to such holder 50,000 shares of common stock. The Company determined that this extension qualified as a modification of the Investor Note rather than an extinguishment. The Company recorded an expense of $126,000 from the issuance of the 556 shares of common stock based on a share price of $22.68. The $22.68 share price was based on a third-party valuation of the company's common stock, with certain adjustments as set forth below in detail in Note 7 – Stockholders' Equity. This expense was recorded to interest expense on the Company's statement of operations for the year ended December 31, 2023.

On August 17, 2023, the Company entered into a second side letter with the holder of the Investor Note (the "August Investor Note Side Letter" and, together with the June Investor Note Side Letter, the "Investor Note Side Letters") pursuant to which the Company (i) amended and restated the Investor Note to extend the maturity date to September 30, 2023 and (ii) in consideration therefor, issued to such holder 30,000 shares of Common Stock. On September 24, 2023, the Company entered into an amendment to the Investor Note, which further extended the maturity date to October 10, 2023. The Investor Note provides for the accrual of interest equal to 2% of the face amount of $450,000 per month ($9,000 per month) and obligates the holder to subscribe for securities in the IPO in full satisfaction of our repayment obligations. In addition, pursuant to the Investor Note Side Letters, the Company agreed to register the 8,890 shares of Common Stock (5,556 issued for the June 23, 2023 side letter, and 3,334 issued for the August 17, 2023 side letter) for resale. The Company recorded an expense of $75,600 from the issuance of the 3,333 shares of common stock based on a share price of $22.68. The $22.68 share price was based on a third-party valuation of the company's common stock, with certain adjustments as set forth below in detail in Note 7 – Stockholders' Equity. This expense was recorded to interest expense on the Company's statement of operations for the year ended December 31, 2023.

Effective October 10, 2023, the Company entered into a side letter with the Holder of the Investor Note, which extended the maturity date of the Investor Note to November 14, 2023 and the Company issued to the Holder of the Investor Note 3,334 shares of Common Stock. The Company recorded additional interest expense of $75,600 from the issuance of the 3,333 shares of common stock based on a share price of $22.68.

Effective November 13, 2023, the Company entered into another side letter with the holder of the Investor Note pursuant to which the Company (i) amended and restated the Investor Note to extend the maturity date to January 31, 2024, and (ii) in consideration therefor, agreed to issue to such Holder of the Investor Note 3,334 shares of Common Stock on each of November 29, 2023, December 29, 2023 and January 29, 2024, provided the Investor Note remained outstanding as of such date. The Company recorded an expense of $75,600 from the issuance of the 3,334 shares of common stock based on a share price of $22.68.

Effective January 30, 2024, the Company entered into another side letter with the holder of the Investor Note (the "January Investor Note Side Letter") pursuant to which the Company (i) amended and restated the Investor Note to extend the maturity date to February 29, 2024, and (ii) in consideration therefor, agreed to issue to such Holder of the Investor Note 77,778 shares of Common Stock on the earlier to occur of the IPO or February 29, 2024. The Investor Note was exchanged for common stock at the time of the Company's IPO.

Director Note

On December 6, 2022, the Company and Mr. Todd Davis, one of the Company's directors, entered into a note payable agreement (the "Director Note") for $175,000. The Director Note had an original issuance discount of $75,000, no other interest and matures on December 31, 2023, or, if earlier to occur, upon the closing of an underwritten offering of securities resulting in at least $15 million in gross proceeds. Mr. Davis, as lender, has the right but not the obligation to subscribe to the underwritten offering by presenting the Director Note in whole or in part to purchase such securities as legal tender therefor, on a dollar-for-dollar basis based upon the offering price of such securities to the public. The Director Note bears no interest except in the case of certain events of default. As of December 31, 2023, the debt discount was fully amortized. There was $72,000 in amortization of debt discount included in interest expense on the statement of operations for the year ended December 31, 2023.

On December 28, 2023, the Company entered into an amendment to the Director Note, which extended the maturity date to February 29, 2024. The Director Note was exchanged for common stock at the time of the Company's IPO.

April Bridge Financing

On April 17, 2023, the Company entered into a bridge loan for working capital purposes, with various accredited investors, all of whom are pre-existing stockholders, in the aggregate principal amount of $393,808 (the "April Bridge Financing"). During the three months ended March 31, 2023, the Company received $166,903 in Advances from certain participating investors. Such Advances accrued interest at a rate of 8% per annum until close of the April Bridge Financing on April 17, 2023, for a total of $1,870 in aggregate interest on all Advances. The April Bridge Financing consisted of senior secured convertible notes that had a maturity date of October 17, 2023. Such notes accrued interest on the unpaid principal amount at a rate of 8% per annum and automatically converted into shares of common stock at the IPO of shares of Common Stock at a 20% discount to the price per IPO Share. The senior secured convertible notes issued in the April Bridge Financing were secured by a security interest in all of our assets (including our patents and intellectual property licenses). In connection with the April Bridge Financing, on April 17, 2023, the Company also entered into a securities purchase agreement with holders of the notes, pursuant to which the Company is required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock received by holders of the notes upon conversion of such notes.

On October 12, 2023, the Company entered into a first amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 1, 2023. On October 24, 2023, the Company entered into a second amendment to the senior secured convertible notes in the April Bridge Financing, which extended the maturity of the notes to November 14, 2023. On November 13, 2023, the Company entered into a third amendment to the senior secured convertible notes in the April Bridge Financing, which further extended the maturity of the notes to February 29, 2024.

September Bridge Financing

On September 1, 2023, the Company entered into a bridge loan for working capital purposes, with various accredited investors, certain of which are pre-existing stockholders, in the aggregate principal amount of $198,128 (the "September Bridge Financing"). The September Bridge Financing consisted of senior secured convertible notes that had a maturity date of March 1, 2024. Such notes accrued interest on the unpaid principal amount at a rate of eight percent (8%) per annum and automatically converted into shares of Common Stock in connection with the IPO at a twenty percent (20%) discount to the price per IPO Share plus an additional 62 shares of Common Stock issuable as further consideration for the September Bridge Financing. The senior secured convertible notes issued in the September Bridge Financing were secured by a security interest in all of our assets (including our patents and intellectual property licenses). In connection with the September Bridge Financing, on September 1, 2023, the Company also entered into a securities purchase agreement with holders of the notes, pursuant to which the Company is required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of Common Stock received by holders of the notes upon conversion of such notes. Additionally, we entered into a subordination and intercreditor agreement, effective September 1, 2023, with the holders of the senior secured convertible notes issued in the April Bridge Financing, pursuant to which those notes and certain liens of the Company would be subordinated to the rights of the holders of the notes issued in the September Bridge Financing.

October Promissory Notes

On October 12, 2023, the Company and four existing investors entered into promissory notes (the "October Promissory Notes") with an aggregate face amount of $210,000 and an aggregate purchase price of $175,000. The October Promissory Notes matured on November 12, 2023 or, if earlier to occur, upon the closing of the IPO. The October Promissory Notes bore no interest except in the case of certain events of default. On November 7, 2023, the Company amended and restated the October Promissory Notes to extend the maturity dates of the October Promissory Notes to November 17, 2023. On November 13, 2023, the Company amended and restated the October Promissory Notes to further extend the maturity dates of the October Promissory Notes to February 29, 2024.

NOTE 7 – STOCKHOLDERS' EQUITY

Stock Split

On February 21, 2024, the Company effected a 9-for-1 reverse stock split. All share and per share amounts have been retrospectively adjusted for the reverse stock split.

Share Forfeiture

Pursuant to the terms of the April Bridge Financing, Chromocell Holdings forfeited 1,203,704 of the shares of common stock of the Company on April 17, 2023. All shareholders with ownership stakes greater than 5% of the Company agreed that the failure to invest its pro rata allocation in the April Bridge Financing would result in the forfeiture of a pro rata percentage of their shares. Chromocell Holdings did not invest its full pro rata allocation, leading to the forfeiture of a portion of their shares of common stock of the Company.

Standby Investor Side letter

On October 11, 2023, the Company entered into a securities purchase agreement with an institutional investor (the "Standby Investor"), pursuant to which (i) the Standby Investor agreed to purchase, upon close of the IPO and at the Company's election, an aggregate of up to 750 shares of Series B Convertible Preferred Stock, par value of $0.0001 per share (the "Series B Preferred Stock") for a purchase price of $ 1,000 per share, and (ii) in consideration therefor, the Company would issue upon close of the IPO, and regardless of whether the Company would have issued any shares of Series B Preferred Stock, an aggregate of 4,167 shares (such shares, the "Standby Shares") of Common Stock to the Standby Investor (such agreement, the "Series B Securities Purchase Agreement"). In addition, pursuant to the Series B Securities Purchase Agreement, the Company was required to file a registration statement within 180 calendar days after consummation of the IPO, providing for the resale of the Standby Shares and shares of Common Stock issuable upon conversion of the Series B Preferred Stock, if issued.

Effective November 13, 2023, the Company entered into a side letter with the Standby Investor (the "Standby Investor Side Letter"), pursuant to which it (i) waived in full the Standby Investor's obligation to fund the aggregate amount to be paid for the Series B Preferred Stock to be purchased under the Series B Securities Purchase Agreement and (ii) agreed to continue to have the obligation to issue the full amount of the Standby Shares upon the closing of the IPO. The Company and the Standby Investor also agreed to terminate each of their obligations solely with respect to the Series B Preferred Stock under the Series B Securities Purchase Agreement and that certain Registration Rights Agreement between the Company and the Standby Investor, which was required to be delivered pursuant to the Series B Securities Purchase Agreement.

Rights Offering

On November 22, 2023, the Company commenced a rights offering (the "Rights Offering") pursuant to which the Company distributed non-transferable subscription rights ("Subscription Rights") to each holder of its Common Stock held as of 5:00 p.m. Eastern Standard Time on November 22, 2023, the record date for the Rights Offering (the "Rights Offering Record Date"). The Subscription Rights could be exercised at any time during the subscription period, which commenced on November 22, 2023 and expired at 5:00 p.m., Eastern Standard Time, on December 1, 2023. Each Subscription Right entitled the eligible holder to purchase up to three shares of the Company's Common Stock at a price per whole share of Common Stock of $0.1008 (the "Subscription Price"). Holders who fully exercised their rights could also subscribe for additional shares of Common Stock not subscribed for by other holders on a pro rata basis. In addition, the Company could distribute to one or more additional persons, at no charge to such person, additional non-transferable subscription rights to purchase shares of its Common Stock in the Rights Offering at the same Subscription Price, without notice to the holders of its Common Stock. Upon the closing of the Rights Offering, the Company issued an aggregate of 2,533,853 shares of Common Stock and received aggregate net proceeds of $255,412, after giving effect to the Representative Affiliate Transactions (as defined below), which it intended to use primarily for general corporate purposes and expenses associated with the IPO.

Options

On January 10, 2023, the Company granted options to acquire 50,002 shares of the Company's common stock to employees and consultants of the Company pursuant to their employment or consulting agreements. These options had a grant date fair value of $1,122,244. These options have an exercise price of $22.68, a term of 10 years, and vest quarterly over ten quarters, with such vesting commencing on October 1, 2022. Since the options began vesting on October 1, 2022, despite being approved by the board of directors on January 10, 2023, the Company applied guidance found in ASC 718-10-55-82 which indicate that the grant date for an award will be the date that a grantee begins to benefit from, or be adversely affected by, subsequent changes in the price of the grantor's equity shares. Since the options began vesting on October 1, 2022, the Company began recording the related expense for the options and recognized the issuance of the options during the year ended December 2022.

On January 10, 2023, the Company granted an option to acquire 2,778 shares of the Company's common stock to a consultant of the Company pursuant to their consulting agreements. This option had a grant date fair value of $62,336. This option has an exercise price of $22.68, a term of 10 years, and vests upon the IPO or sale of the Company.

On January 10, 2023, the Company issued a total of 88,891 options to purchase shares of the Company's common stock to several of its directors, pursuant to their continued service as a director. These options had a grant date fair value of $1,994,768. These options have an exercise price of $22.68, a term of 10 years, and 66,668 of these options will vest over 2.5 years commencing on January 10, 2023, and 22,223 of the options will vest upon the Company's establishment of a second clinical program, which shall include an acquisition or entrance into a joint venture. During the year ended December 31, 2023, the Company recorded $1,097,122 in stock compensation for the options that vested during the period.

On March 9, 2023, the Company issued an option to acquire 15,000 shares of the Company's common stock to a director, pursuant to their continued service as a director. This option had a grant date fair value of $336,606. This option has an exercise price of $22.68, a term of 10 years, and will vest over 2.25 years commencing on March 9, 2023.

On May 15, 2023, the Company issued an option to acquire 27,778 shares of the Company's common stock to a director, pursuant to their continued service as a director. This option had a grant date fair value of $623,057. This option has an exercise price of $22.68, a term of 10 years, and vests upon the IPO or sale of the Company.

On May 15, 2023, the Company issued an option to acquire 24,223 shares of the Company's common stock to a director, pursuant to their continued service as a director. This option had a grant date fair value of $543,306. This option has an exercise price of $22.68, a term of 10 years, and will vest over 3 years.

During the year ended December 31, 2023, the fair value of each stock option granted was estimated using the Black-Scholes Option Pricing Model using the following inputs:

Exercise price	$ 22.68
Expected dividend yield	0%
Risk free interest rate	3.50-3.93%
Expected life in years	10
Expected volatility	157-158%

The risk-free interest rate assumption for options granted is based upon observed interest rates on the United States Government Bond Equivalent Yield appropriate for the expected term of the options.

With certain adjustments outlined below, the Company based its determination of the underlying fair value of the Company's common stock on the findings of an independent third party engaged by the Company to determine the fair value of the Company's intellectual property. The Company had the analysis conducted in conjunction with the Contribution Agreement, which was executed on August 10, 2022. The analysis determined that the fair value of the Company's intellectual property was $44.8 million. At the time of the Contribution Agreement and the option grants, there was 1,187,302 shares (on an as converted basis reflecting the conversion of the 600,000 Series A Convertible Preferred Stock held by Chromocell Holdings). As of December 31, 2023, none of these shares have been converted. The resulting value per common share was $37.71. The Company then adjusted this value in accordance with the following:

Value of intellectual property	$ 44.8 million
Common shares outstanding (as converted)	1,187,302
Value per common share	$ 37.71
Illiquidity discount	20%
Minority discount	20%
Fair value of the common stock	$ 22.68

The Company determined the expected volatility assumption for options granted using the historical volatility of comparable public companies' common stock. The Company will continue to monitor peer companies and other relevant factors used to measure expected volatility for future option grants, until such time that the Company's common stock has enough market history to use historical volatility.

The dividend yield assumption for options granted is based on the Company's history and expectation of dividend payouts. The Company has never declared nor paid any cash dividends on its common stock, and the Company does not anticipate paying any cash dividends in the foreseeable future.

The Company recognizes option forfeitures as they occur as there is insufficient historical data to accurately determine future forfeiture rates.

The following is an analysis of the stock option grant activity:

	Number	Weighted Average Exercise Price	Weighted Average Remaining Life
Stock Options			
Outstanding December 31, 2022	50,002	$ 22.68	9.76
Granted	158,670	$ 22.68	9.16
Expired	(11,112)	$ 22.68	—
Exercised	—	$ —	—
Outstanding December 31, 2023	197,560	$ 22.68	9.08
Exercisable December 31, 2023	84,131	$ 22.68	8.98

A summary of the status of the Company's nonvested options as of December 31, 2023, and changes during the year ended December 31, 2023, is presented below:

Non-vested Options	Options	Weighted-Average Exercise Price
Non-vested at December 31, 2022	45,556	$ 22.68
Granted	158,670	$ 22.68
Vested	(90,797)	$ 22.68
Forfeited	—	$ —
Non-vested at December 31, 2023	113,429	$ 22.68

The total number of options granted during the year ended December 31, 2023 and 2022 was 197,560 and 0, respectively. The exercise price for these options was $22.68 per share and there was an intrinsic value of $ 0.

The Company recognized stock-based compensation expense related to option vesting amortization of $ 1,733,233 and $110,146 for the years ended December 31, 2023 and 2022, respectively, which is included in general and administrative expenses in the statement of operations.

As of December 31, 2023, the unamortized stock option expense was $ 1,854,280. As of December 31, 2023, the weighted average period for the unamortized stock compensation to be recognized is 2.91 years.

On June 23, 2023, the Company and Camden Capital LLC amended and restated the Consultant Agreement by entering into an Amended and Restated Consultant Agreement, whereby the RSU for 16,667 shares of common stock was cancelled, and the Company agreed to grant Camden Capital LLC an option to acquire 27,778 shares of common stock within 30 days of the closing of the IPO. As of June 23, 2023, such RSU for 16,667 shares of common stock had not vested, and no expense was recorded on the Company's financial statements.

NOTE 8 – LICENSE AGREEMENT

Benuvia License Agreement

On December 23, 2023, the Company entered into an exclusive licensing agreement (the "Benuvia License Agreement") with Benuvia Operations, LLC ("Benuvia") for a sublingual formulation of a Diclofenac spray for the treatment of acute pain, a Rizatriptan sublingual spray formulation and an Ondansetron sublingual spray formulation (collectively, the "Spray Formulations"), diversifying its pipeline of non-opioid pain treatment therapies, while adding therapeutic options for related conditions. The Diclofenac Spray Formulation is patented and has started clinical development in human volunteers. Under the terms of the Benuvia License Agreement, Benuvia will be responsible for the manufacturing and supply of the Spray Formulations, but the Company will have exclusive, worldwide rights to develop, commercialize and distribute the Spray Formulations.

In connection with the Benuvia License Agreement, the Company agreed to pay Benuvia a 6.5% royalty on net sales of the Spray Formulations for a period of up to 15 years from the date of the first commercial sale of any of the Spray Formulations. In addition, on December 23, 2023, the Company entered into a stock issuance agreement with Benuvia pursuant to which the Company agreed to issue Benuvia 384,226 shares of the Company's Common Stock.

The issuance of 384,226 shares of the Company's Common Stock to Benuvia was negotiated between the parties based on an agreed upon determination of the reasonable value of the Spray Formulations. After determining the reasonable value of the Spray Formulations based on a variety of factors, including the potential pricing for the IPO transaction, the Company proposed a number of shares to Benuvia. Feedback on the valuation by both underwriters involved their understanding of the capital markets, the life science sector and peer companies to the Company in that sector. During the year ended December 31, 2023, the Company recognized $2.2 million in licensing expenses which is recognized in R&D expenses on the Company's statement of operations.

Mr. Davis, one of our directors, serves as the Chairman and Chief Executive Officer of Benuvia Holdings, LLC, which is the ultimate parent company of Benuvia.

NOTE 9 – INCOME TAX

The Company follows the asset and liability method of accounting for income taxes under ASC 740, "Income Taxes." Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of December 31, 2020. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position. The Company is subject to income tax examinations by major taxing authorities since inception. The Company used the separate return method for the preparation of the income tax provision.

For the years ended December 31, 2023 and 2022, there was no income tax provision recorded. The tax benefit was added to the net operating loss to which a full valuation allowance was applied.

A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to income taxes as reflected in the financial statements is as follows:

	2023	2023
Income taxes at U.S. statutory rate	19.11%	19.11%
Income taxes at state rate	9.00%	9.00%
Change in valuation allowance	(28.11)%	(28.11)%
Total provision for income taxes	—%	—%

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities as of December 31, 2023 and 2022 are comprised of the following:

	December 31,	
	2023	2022
Deferred tax assets		
Net operating loss carryforwards	$ 2,248,163	$ 1,763,875
Stock-based compensation	518,174	30,962
Accrued compensation	181,576	62,369
Capitalized organizational costs	22,016	—
Capitalized intellectual property costs	620,440	—
Interest expense limitation	36,202	—
Total deferred tax assets	3,626,571	1,857,206
Valuation allowance	(3,626,571)	(1,857,206)
Net deferred tax assets	—	—
Deferred tax liabilities		
Total deferred tax liabilities	—	—
Net deferred taxes	$ —	$ —

For the years ended December 31, 2023 and 2022, the Company recorded a full valuation allowance of its deferred tax assets.

The previously reported deferred tax components, including the valuation allowance, totalling $4,053,204 for the year ended December 31, 2022 have been revised as disclosed in the table above.

The Company has a net operating loss carryforward for federal tax purposes totalling approximately $ 8.0 million at December 31, 2023. Approximately $8.0 million net operating losses incurred in fiscal 2018 through fiscal 2023 that do not expire and can be utilized to offset up to 80% of future taxable income under the Tax Cuts and Jobs Act.

Utilization of NOL and tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by the Internal Revenue Code (the "Code"), as amended, as well as similar state provisions. In general, an "ownership change" as defined by the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percent of the outstanding stock of a company by certain stockholders or public groups.

NOTE 10 – SUBSEQUENT EVENTS

Initial Public Offering

On February 21, 2024, the Company consummated the IPO and issued and sold 1,100,000 shares of Common Stock at a price to the public of $ 6.00 per share. The aggregate net proceeds from the IPO were approximately $5.7 million after deducting underwriting discounts and commissions and offering expenses.

Bridge Financing Note Amendments and Recission Agreement

On February 8, 2024, the Company and certain affiliates of A.G.P./Alliance Global Partners ("A.G.P.") entered into amendments to the senior secured convertible notes issued to such affiliates of the A.G.P. in the April Bridge Financing and September Bridge Financing to remove the automatic conversion features from such notes (the "Bridge Financing Note Amendments"). Under the Bridge Financing Note Amendments, both notes issued in the April Bridge Financing and the September Bridge Financing have a maturity date of March 1, 2024, and the full principal amount of both notes and any accrued interest thereon shall be payable solely in cash upon the consummation of the IPO. Both notes have an annual interest rate of 8%, which accrues daily, and is calculated on the basis of a 360-day year (consisting of twelve 30 calendar day periods), giving an effective interest rate of 8.3%.

On February 10, 2024, the Company entered into a Stock Rescission Agreement with certain affiliates of A.G.P. (the "Stock Rescission Agreement" and, together with the Bridge Financing Note Amendments, the "Representative Affiliate Transactions"), pursuant to which the Company rescinded 111,129 shares of Common Stock held by such affiliates of A.G.P. and agreed to refund an aggregate of $91,513 paid by such affiliates of A.G.P. in consideration therefor within 30 days of the effective date of the Stock Rescission Agreement.

Amendment to Investor Note

Effective January 30, 2024, the Company entered into another side letter with the holder of the Investor Note (the "January Investor Note Side Letter") pursuant to which the Company (i) amended and restated the Investor Note to extend the maturity date to February 29, 2024, and (ii) in consideration therefor, agreed to issue to such Holder of the Investor Note 77,778 shares of Common Stock on the earlier to occur of the IPO or February 29, 2024.

Appointment of Francis Knuettel II as Chief Executive Officer

Effective March 13, 2024, our board of directors has appointed Francis Knuettel II as Chief Executive Officer of the Company. Mr. Knuettel will serve as the Company's Chief Executive Officer until a successor is duly elected and qualified, unless sooner removed. In addition to his role as Chief Executive Officer of the Company, Mr. Knuettel will continue to serve in his capacity as Chief Financial Officer, Treasurer and Secretary of the Company.

Complaint Filed by New Jersey Economic Development Authority

On April 9, 2024, we received correspondence notifying us of an Entry of Default Notice, filed on April 8, 2024, against "Chromocell Corporation d/b/a Chromocell Therapeutics" in the matter *New Jersey Economic Development Authority v. Chromocell Corporation, et al.* (Docket No. MER-L-001748-23). The complaint filed by the New Jersey Economic Development Authority (the "EDA") on September 12, 2023 in the Superior Court of New Jersey Law Division, Mercer County, alleges Chromocell Holdings' (not the Company's) breach of a Settlement Agreement between the EDA and Chromocell Holdings, dated December 31, 2022 (the "Settlement Agreement"), pursuant to which EDA and Chromocell Holdings agreed that Chromocell Holdings would (i) vacate the premises located at 671 US Highway One South, North Brunswick, New Jersey, on or before December 31, 2023, (ii) pay an initial lump-sum payment of $10,000 toward outstanding rent and provide a copy of its IPO Registration Statement and (iii) make a final one-time lump sum payment to the EDA of $510,701 to satisfy Chromocell Holdings' outstanding rent and additional rent obligations within 90 days of Chromocell Holdings' executing the Settlement Agreement or within 15 days of Chromocell Holdings' IPO, whichever was the first to occur. The complaint alleges Chromocell Holdings' breach of each of these provisions of the Settlement Agreement and sought a judgment for the entire amount due and owing as of September 12, 2023 ($510,701), compensatory damages, pre-judgment interest, attorney's fees, costs of suit and such other and further relief as the court deems just and proper. Besides including "Chromocell Therapeutics" in the case caption, the complaint does not include allegations related to any action purportedly taken by the Company. While the complaint appears to concern a matter between Chromocell Holding and EDA, the Company steadfastly believes it was inappropriately named as a defendant and intends to file a motion to vacate the Entry of Default and have "Chromocell Therapeutics" dismissed from the matter.

Exhibit 3.3

CERTIFICATE OF DESIGNATION OF
SERIES C CONVERTIBLE REDEEMABLE PREFERRED STOCK OF
CHROMOCELL THERAPEUTICS CORPORATION

Pursuant to Section 151 of the General Corporation Law of the State of Delaware (the " **DGCL**"), Chromocell Therapeutics Corporation, a corporation organized and existing under the General Corporation Law of the State of Delaware (the "**Corporation**"), in accordance with the provisions of Section 103 thereof, does hereby submit the following:

WHEREAS, the Amended and Restated Certificate of Incorporation of the Corporation (the " **Certificate of Incorporation**") authorizes the issuance of up to 20,000,000 shares of preferred stock, par value $0.0001 per share, of the Corporation ("**Preferred Stock**"), issuable from time to time in one or more series, and expressly authorizes the Board of Directors of the Corporation (the "**Board**"), to fix the dividend rights, dividend rate, voting rights, conversion rights, rights and terms of redemption and liquidation preferences of any wholly unissued series of preferred stock and the number of shares constituting any series and the designation thereof, of any of them; and

WHEREAS, it is the desire of the Board, pursuant to its authority as aforesaid, to establish and fix the number of shares to be included in a new series of Preferred Stock and the designation, rights, preferences and limitations of the shares of such new series.

NOW, THEREFORE, BE IT RESOLVED, that the Board does hereby provide for a new series of Preferred Stock and does hereby in this Certificate of Designation (this "**Certificate of Designation**") establish and fix and herein state and express the designation, rights, preferences, powers, restrictions and limitations of such new series of Preferred Stock as follows:

1. Number and Designation. There shall be a series of Preferred Stock that shall be designated as the "Series C Convertible Redeemable Preferred Stock" of the Corporation (the "**Series C Preferred Stock**") and the number of authorized Shares constituting such series shall be 5,000 Shares. The number of authorized shares of Series C Preferred Stock may from time to time be increased (but not in excess of the total number of authorized shares of Preferred Stock, less all shares of any other series of Preferred Stock authorized at the time of such increase) or decreased (but not below the number of shares of Series C Preferred Stock then outstanding). Shares of Series C Preferred Stock that are redeemed, repurchased or otherwise acquired by the Corporation will be cancelled and shall revert to authorized but unissued shares of Preferred Stock undesignated as to series. The Corporation shall have the right to re-open this series and issue additional share of the Series C Preferred Stock either through public or private sales at any time and from time to time without notice to or the consent of holders of the Series C Preferred Stock. The additional shares of the Series C Preferred Stock will be deemed to form a single series with the Series C Preferred Stock issued under this Certificate of Designation. Each Share shall have a par value of $0.0001 per share. The powers, preferences, rights, qualifications, limitations and restrictions of the Series C Preferred Stock shall be as set forth herein.

2. Defined Terms. For purposes hereof, the following terms shall have the following meanings:

"**Affiliate**" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 of the Securities Act.

"**Attribution Parties**" has the meaning set forth in **Section 6.6**.

"**Board**" has the meaning set forth in the Recitals hereof.

"**Beneficial Ownership Limitation**" has the meaning set forth in **Section 6.6**.

"**Certificate of Designation**" has the meaning set forth in the Recitals hereof.

"**Certificate of Incorporation**" has the meaning set forth in the Recitals hereof.

"**Common Stock**" means the common stock, par value $0.0001 per share, of the Corporation.

"**Company Notice of Redemption**" has the meaning set forth in **Section 9.2**.

"**Company Redemption**" has the meaning set forth in **Section 9.1**.

"**Company Redemption Date**" has the meaning set forth in **Section 9.1**.

"**Company Redemption Notice Period**" has the meaning set forth in **Section 9.2**.

"**Conversion Notice**" has the meaning set forth in **Section 6.4**.

"**Corporation**" has the meaning set forth in the Preamble hereof.

"**Dividends**" has the meaning set forth in **Section 3**.

"**DGCL**" has the meaning set forth in the Preamble hereof.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, or any successor federal statute, and the rules and regulations thereunder, which shall be in effect at the time.

"**Holder**" means a holder of Series C Preferred Stock.

"**Initial Issuance Date**" has the meaning set forth in **Section 3**.

"**Junior Securities**" has the meaning set forth in **Section 5.1**

"**Liquidation**" has the meaning set forth in **Section 5**.

"**New York Courts**" has the meaning set forth in **Section 11.1**.

"**Person**" means an individual, corporation, partnership, joint venture, limited liability company, governmental authority, unincorporated organization, trust, association or other entity.

"**Preferred Stock**" has the meaning set forth in the Recitals.

"**Preferred Stock Certificates**" has the meaning set forth in **Section 6.4**.

"**IPO**" means the sale, in a firm commitment public underwritten offering pursuant to an effective registration statement under the Securities Act, of securities of the Corporation, following which such securities (or any component part thereof) are listed on a national securities exchange registered with the SEC under Section 6(a) of the Exchange Act (or, alternatively, quoted on the OTC Bulletin Board or similar quotation system).

"**IPO Price**" means the price at which the Common Stock is sold to the public in the IPO.

"**Required Holders**" has the meaning set forth in **Section 8**.

"**SEC**" means the U.S. Securities and Exchange Commission.

"**Securities Act**" means the Securities Act of 1933, as amended, or any successor federal statute, and the rules and regulations thereunder, which shall be in effect at the time.

"**Series C Preferred Stock**" has the meaning set forth in **Section 1**.

"**Share**" means a share of Series C Preferred Stock.

"**Stated Value**" shall mean $1,000.00 per Share, subject to adjustment for stock splits, stock dividends, recapitalizations, reorganizations, reclassifications, combinations, subdivisions or other similar events occurring after the Initial Issuance Date with respect to the Shares.

"**Trading Day**" means a day on which the Trading Market for the Common Stock is open for trading.

"**Trading Market**" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange (or any successors to any of the foregoing).

"**Transfer Agent**" has the meaning set forth in **Section 6.4**.

3. Dividends. Holders shall not be entitled to receive any dividends in respect of the Series C Preferred Stock.

4. Voting Rights. Except as otherwise provided herein or as otherwise provided by the DGCL, the Series C Preferred Stock shall have no voting rights.

5. Rank; Liquidation.

5.1. Rank. The Series C Preferred Stock shall rank (i) senior to the Common Stock and any class or series of capital stock of the Corporation created specifically ranking by its terms junior to the Series C Preferred Stock (collectively, the "**Junior Securities**"); and (ii) junior to any class or series of capital stock of the Corporation hereafter created specifically ranking by its terms senior to any Series C Preferred Stock, in each case, with respect to payment of dividends and distributions of assets upon liquidation, dissolution or winding up of the Corporation, whether voluntarily or involuntarily (a "**Liquidation**").

5.2. Liquidation. In the event of a Liquidation, the Holders of Shares then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders, before any payment shall be made to the holders of Junior Securities by reason of their ownership thereof, an amount in cash equal to the aggregate Stated Value of all Shares held by such Holder.

5.3. Notice. In the event of any Liquidation, the Corporation shall, within five (5) days of the date the Board approves such action, or no later than five (5) days of any stockholders' meeting called to approve such action, or within five (5) days of the commencement of any involuntary proceeding, whichever is earlier, give each Holder written notice of the proposed action. Such written notice shall describe the material terms and conditions of such proposed action, including a description of the stock, cash and property to be received by the Holder upon consummation of the proposed action and the date of delivery thereof. If any material change in the facts set forth in the initial notice shall occur, the Corporation shall promptly give written notice to each Holder of such material change.

6. Conversion. Subject to the provisions of Section 6.6, at any time after the Initial Issuance Date, each share shall be convertible into validly issued, fully paid and non-assessable shares of Common Stock, on the terms and conditions set forth in this Section 6.

6.1. Holder's Conversion Right. Subject to the provisions of Sections 6.3 and 6.6, at any time or times on or after the closing of the IPO, each Holder shall be entitled to convert any portion of the outstanding Shares held by such Holder into an aggregate number of shares of Common Stock determined by (i) multiplying the number of Shares to be converted by the Stated Value of the Series C Preferred Stock, and then (ii) dividing the value obtained from the preceding clause (i) by 125% of the IPO Price. The Corporation shall not issue any fraction of a share of Common Stock upon any conversion. If the issuance would result in the issuance of a fraction of a share of Common Stock, the Corporation shall round such fraction of a share of Common Stock up to the nearest whole share. The Corporation shall pay any and all transfer, stamp, issuance and similar taxes, costs and expenses (including, without limitation, fees and expenses of the Transfer Agent (as defined below)) that may be payable with respect to the issuance and delivery of Common Stock upon conversion of any Conversion Amount.

6.2. Mandatory Conversion. If the Common Stock trades on a Trading Market for twenty (20) consecutive Trading Days above 175% of the IPO Price, the Series C Preferred Stock shall mandatorily convert into an aggregate number of shares of Common Stock determined by (i) multiplying the number of Shares issued and outstanding by the Stated Value of the Series C Preferred Stock, and then (ii) dividing the value obtained from the preceding clause (i) by 120% of the IPO Price. The Corporation shall provide written notice to the Holder of the mandatory conversion at least one (1) day prior to the date of mandatory conversion. All shares of capital stock issued hereunder by the Corporation shall be duly and validly issued, fully paid and nonassessable, and free and clear of all taxes, liens, charges and encumbrances with respect to the issuance thereof. Any fractional shares of Common Stock resulting from such determination shall be rounded up to the next whole number.

6.3. Lock-Up. The Shares and the shares of Common Stock received pursuant to Sections 6.1 and 6.2 shall be subject to customary lock-up provisions as requested by the underwriters of the IPO.

6.4. Mechanics of Holder's Conversion. Subject to Section 6.6, the conversion of any Share by the Holder pursuant to Section 6.1shall be conducted in the following manner:

(a) Holder's Conversion Right. To convert Shares into shares of Common Stock on any date (a " **Conversion Date**") pursuant to Section 6.1, a Holder shall deliver (whether via facsimile or electronic mail), for receipt on or prior to 11:59 p.m., New York time, on such date, an electronic copy of an executed notice of conversion of the Share(s) subject to such conversion in the form attached hereto as Exhibit I (the "**Conversion Notice**") to the Corporation. Within (3) Trading Days following a conversion of any such Shares as aforesaid, such Holder, if Holder is holding a physical certificate, shall surrender to a nationally recognized overnight delivery service for delivery to the Corporation the original certificates representing the Shares (the "**Preferred Stock Certificates**") so converted as aforesaid (or an indemnification undertaking with respect to the Shares in the case of its loss, theft or destruction). On or before the first (1st) Trading Day following the date of receipt of a Conversion Notice, the Corporation shall transmit by facsimile or electronic mail an acknowledgment of confirmation, in the form attached hereto as Exhibit II, of receipt of such Conversion Notice to such Holder and the Corporation's transfer agent (the "**Transfer Agent**"), which confirmation shall constitute an instruction to the Transfer Agent to process such Conversion Notice in accordance with the terms herein. On or before the first (1st) Trading Day following the date of receipt of a Conversion Notice (or such earlier date as required pursuant to the Exchange Act or other applicable law, rule or regulation for the settlement of a trade initiated on the applicable Conversion Date of such shares of Common Stock issuable pursuant to such Conversion Notice), the Corporation shall (1) provided, that the Transfer Agent is participating in the Depository Trust Corporation ("**DTC**") Fast Automated Securities Transfer Program, credit such aggregate number of shares of Common Stock to which such Holder shall be entitled to such Holder's or its designee's balance account with DTC through its Deposit/Withdrawal at Custodian system, or (2) if the Transfer Agent is not participating in the DTC Fast Automated Securities Transfer Program, issue and deliver (via reputable overnight courier) to the address as specified in such Conversion Notice, a certificate, registered in the name of such Holder or its designee, for the number of shares of Common Stock to which such Holder shall be entitled. If the number of Shares represented by the Preferred Stock Certificate(s) submitted for conversion is greater than the number of Shares being converted, then the Corporation shall, as soon as practicable and in no event later than three (3) Trading Days after receipt of the Preferred Stock Certificate(s) and at its own expense, issue and deliver to such Holder (or its designee) a new Preferred Stock Certificate representing the number of Shares not converted. The Person or Persons entitled to receive the shares of Common Stock issuable upon a conversion of Shares shall be treated for all purposes as the record holder or holders of such shares of Common Stock on the Conversion Date.

(b) Legend. Each Preferred Stock Certificate shall bear the following legend:

THE SECURITIES REFERENCED HEREIN HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH SALE OR DISTRIBUTION MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE CORPORATION THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933.

6.5. Effect of Conversion. All Shares converted as provided in this **Section 6** shall no longer be deemed outstanding as of the effective time of the applicable conversion and all rights with respect to such Shares shall immediately cease and terminate as of such time.

6.6. Beneficial Ownership Limitation. Notwithstanding anything to the contrary set forth herein, the Corporation shall not effect any conversion of the Series C Preferred Stock, and a Holder shall not have the right to convert any portion of the Series C Preferred Stock, to the extent that, after giving effect to the conversion, such Holder (together with such Holder's Affiliates, and any Persons acting as a group together with such Holder or any of such Holder's Affiliates (such Persons, "**Attribution Parties**")) would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by such Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon conversion of the Series C Preferred Stock with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which are issuable upon (i) conversion of the remaining, unconverted Series C Preferred Stock beneficially owned by such Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Corporation subject to a limitation on conversion or exercise analogous to the limitation contained herein (including, without limitation, the Series C Preferred Stock) beneficially owned by such Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 6.6, beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. To the extent that the limitation contained in this Section 6.6 applies to any conversion pursuant to Section 6.1, the determination of whether the Series C Preferred Stock is convertible (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and of how many shares of Series C Preferred Stock are convertible shall be in the sole discretion of such Holder, and the submission of a Notice of Conversion shall be deemed to be such Holder's determination of whether the shares of Series C Preferred Stock may be converted (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and how many shares of the Series C Preferred Stock are convertible, in each case subject to the Beneficial Ownership Limitation. To ensure compliance with this restriction, each Holder will be deemed to represent to the Corporation each time it delivers a Notice of Conversion that such Notice of Conversion has not violated the restrictions set forth in this Section 6.6 and the Corporation shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 6.6, in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as stated in the most recent of the following: (i) the Corporation's most recent periodic or annual report filed with the Commission, as the case may be, (ii) a more recent public announcement by the Corporation or (iii) a more recent written notice by the Corporation or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request (which may be via email) of a Holder, the Corporation shall within one (1) Trading Day confirm orally and in writing to such Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Corporation, including the Series C Preferred Stock, by such Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "**Beneficial Ownership Limitation**" shall be 4.99% (or, upon election by a Holder prior to the issuance of any shares of Series C Preferred Stock, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon conversion of Series C Preferred Stock held by the applicable Holder. A Holder, upon notice to the Corporation, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 6.6 applicable to its Series C Preferred Stock; provided, that the Beneficial Ownership Limitation shall not in any event exceed 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon conversion of this Series C Preferred Stock held by the Holder and the provisions of this Section 6.6 shall continue to apply. Any such increase will not be effective until the 61st day after such notice is delivered to the Corporation and shall only apply to such Holder and no other Holder. The Beneficial Ownership Limitation shall not be waived by the Corporation or the Holder and upon issuance of the Series C Preferred Stock by the Corporation, and the purchase thereof by the Holder, each of the Corporation and the Holder shall be deemed to acknowledge such limitation and to agree not to waive it. The provisions of this Section 6.6 shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 6.6 to correct this Section 6.6 (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation contained herein or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this Section 6.6 shall apply to any successor or assign of a Holder. Notwithstanding the foregoing, upon mandatory conversion pursuant to Section 6.2, the shares of Common Stock issuable upon conversion of the Series C Preferred Stock subject to the mandatory conversion that would exceed the Beneficial Ownership Limitation shall be held in abeyance until issuable in accordance with the Beneficial Ownership Limitation.

7. Notices. Except as otherwise provided herein, all notices, requests, consents, claims, demands, waivers and other communications hereunder shall be in writing and shall be deemed to have been given: (a) when delivered by hand (with written confirmation of receipt); (b) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested); (c) on the date sent by facsimile or e-mail of a PDF document (with confirmation of transmission) if sent during normal business hours of the recipient, and on the next business day if sent after normal business hours of the recipient; or (d) on the third (3rd) day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications must be sent (a) to the Corporation, at its principal executive offices and (b) to any stockholder, at such holder's address at it appears in the stock records of the Corporation (or at such other address for a stockholder as shall be specified in a notice given in accordance with this **Section 7**).

8. Amendment and Waiver. No provision of this Certificate of Designation may be amended, modified or waived except by an instrument in writing executed by the Corporation and the holders of at least a majority of the then outstanding Shares (the "**Required Holders**"), and any such written amendment, modification or waiver will be binding upon the Corporation and each holder of Series C Preferred Stock; *provided*, *further*, that no amendment, modification or waiver of the terms or relative priorities of the Series C Preferred Stock may be accomplished by the merger, consolidation or other similar transaction of the Corporation with another corporation or entity unless the Corporation has obtained the prior written consent of the Required Holders in accordance with this **Section 8**.

9. Company Redemption.

9.1. On any date after the Initial Issuance Date (each, a "**Company Redemption Date**"), the Corporation, at its sole discretion, may redeem all or any portion of the then-outstanding Shares for cash (each, a "**Company Redemption**"); provided, however, that the Corporation may not affect any Company Redemption with respect to any Share on a Company Redemption Date that precedes the expiration of the lock-up period requested by the underwriters of the IPO without first obtaining the consent of the Holder of the Share subject to redemption). The redemption price per Share to be paid by the Corporation in connection with a Company Redemption shall be equal to the Stated Value of such Share.

9.2. To effect a Company Redemption, the Corporation shall send to the Holders a written notice (i) notifying the Holders of the election of the Corporation to redeem all or any portion of the Shares and the applicable Company Redemption Date, (ii) stating the place or places at which the Shares shall, upon presentation and surrender of the Preferred Stock Certificate(s) evidencing such Shares, be redeemed (and other instructions a Holder must follow to receive payment), and (iii) stating the redemption price therefor, as provided in Section 9.1 hereof (such notice, a "**Company Notice of Redemption**"). The Company Redemption Date selected by the Corporation shall be no less than three (3) Trading Days and no more than twenty (20) Trading Days after the date on which the Corporation provides the Company Notice of Redemption to the Holders (such period, a "**Company Redemption Notice Period**"). Each Holder shall be entitled to convert all or any portion of the Shares subject to the Company Notice of Redemption held by such Holder, after receiving the Company Notice of Redemption but prior to the end of the Company Redemption Notice Period, in accordance with Section 6.4 hereof.

9.3. From and after the time at which any Shares are called for redemption in accordance with Sections 9.1 and 9.2 above, such Shares shall cease to be outstanding, and the only right of the former Holders of such Shares, as such, will be to receive the applicable redemption price. The Shares redeemed by the Corporation pursuant to this Certificate of Designation shall, upon such redemption, be automatically retired and restored to the status of authorized but unissued shares of Preferred Stock.

10. [Reserved].

11. Miscellaneous.

11.1. Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Certificate of Designation shall be governed by and construed and enforced in accordance with the internal laws of the State of Delaware, without regard to the principles of conflict of laws thereof. All legal proceedings concerning the interpretation, enforcement and defense of the transactions contemplated by this Certificate of Designation (whether brought against a party hereto or its respective Affiliates, directors, officers, shareholders, employees or agents) shall be commenced in the state and federal courts sitting in the City of New York, Borough of Manhattan (the "**New York Courts**"). The Corporation and each holder hereby irrevocably submits to the exclusive jurisdiction of the New York Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of such New York Courts, or such New York Courts are improper or inconvenient venue for such proceeding. The Corporation and each holder hereby irrevocably waive personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Certificate of Designation and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by applicable law. The Corporation and each holder hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Certificate of Designation or the transactions contemplated hereby. If any party shall commence an action or proceeding to enforce any provisions of this Certificate of Designation, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding.

11.2. Waiver. Any waiver by the Corporation or a Holder of a breach of any provision of this Certificate of Designation shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Certificate of Designation or a waiver by any other Holders. The failure of the Corporation or a Holder to insist upon strict adherence to any term of this Certificate of Designation on one or more occasions shall not be considered a waiver or deprive that party (or any other Holder) of the right thereafter to insist upon strict adherence to that term or any other term of this Certificate of Designation on any other occasion. Any waiver by the Corporation or a Holder must be in writing.

11.3. Severability. If any provision of this Certificate of Designation is invalid, illegal or unenforceable, the balance of this Certificate of Designation shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law.

11.4. Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a business Day, such payment shall be made on the next succeeding business day.

11.5. Headings. The headings contained herein are for convenience only, do not constitute a part of this Certificate of Designation and shall not be deemed to limit or affect any of the provisions hereof.

****

RESOLVED FURTHER, that the Interim Chief Executive Officer and Chief Financial Officer of the Corporation be and he hereby is authorized and directed to prepare and file this Certificate of Designation in accordance with the foregoing resolution and the provisions of Delaware law.

IN WITNESS WHEREOF, the undersigned have executed this Certificate of Designation this 15th of February, 2024.

CHROMOCELL THERAPEUTICS CORPORATION

By: /s/ Francis Knuettel II
Name: Francis Knuettel II
Title: Interim Chief Executive Officer and Chief Financial Officer

EXHIBIT I

CHROMOCELL THERAPEUTICS CORPORATION

CONVERSION NOTICE

Reference is made to the Certificate of Designations of the Series C Convertible Redeemable Preferred Stock of Chromocell Therapeutics Corporation (the "**Certificate of Designations**"). In accordance with and pursuant to the Certificate of Designations, the undersigned hereby elects to convert the number of shares of Series C Preferred Stock, $0.0001 par value per share (the "**Preferred Shares**"), of Chromocell Therapeutics Corporation, a Delaware corporation (the "**Corporation**"), indicated below into shares of common stock, $0.0001 par value per share (the " **Common Stock**"), of the Corporation, as of the date specified below.

Date of Conversion: _____

Aggregate number of Preferred Shares to be converted: _____

Aggregate Stated Value of such Preferred Shares to be converted: _____

Aggregate accrued and unpaid Dividends and accrued and unpaid Late Charges with respect to such Preferred Shares and such Aggregate Dividends to be converted: _____

AGGREGATE CONVERSION AMOUNT TO BE CONVERTED: _____

Please confirm the following information:

Conversion Price: _____

Number of shares of Common Stock to be issued: _____

Please issue the Common Stock into which the applicable Preferred Shares are being converted to Holder, or for its benefit, as follows:

☐ Check here if requesting delivery as a certificate to the following name and to the following address:

Issue to: _____

_____

_____

☐ Check here if requesting delivery by Deposit/Withdrawal at Custodian as follows:

DTC Participant: _____

DTC Number: _____

Account Number: _____

Date: _____ __,

Name of Registered Holder

By:
Name:
Title:

Tax ID:_____

Facsimile:_____

E-mail Address:

EXHIBIT II

ACKNOWLEDGMENT

The Corporation hereby acknowledges this Conversion Notice and hereby directs _____ to issue the above indicated number of shares of Common Stock in accordance with the Transfer Agent Instructions dated _____, 202__ from the Corporation and acknowledged and agreed to by _____.

[_____]

By: _____
Name:
Title:

Exhibit 4.2

DESCRIPTION OF SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2023, Chromocell Therapeutics Corporation (the "Company," "we," "us" or "our") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock, par value $0.0001 per share (our "Common Stock").

General

The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation (our "Charter") and our Amended and Restated Bylaws (our "Bylaws"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.2 is a part. Copies of these documents can be accessed through hyperlinks to those documents in the list of exhibits in our Annual Report on Form 10-K for the fiscal year ending December 31, 2023. We encourage you to read our Charter, our Bylaws, and the applicable provisions of the Delaware General Corporation Law (the "DGCL") for additional information.

Authorized Capital Shares

Our authorized capital shares consist of (a) 200,000,000 shares of Common Stock and (b) 20,000,000 shares of "blank check" preferred stock, par value $0.0001 per share (our "Preferred Stock"). The outstanding shares of our Common Stock are fully paid and nonassessable.

Voting Rights

The holders of shares of Common Stock vote together as one class on all matters as to which holders of Common Stock are entitled to vote. Except as otherwise required by applicable law, all voting rights are vested in and exercised by the holders of Common Stock with each share of Common Stock being entitled to one vote, including in all elections of directors. The vote of the holders of a majority of the issued and outstanding shares of Common Stock entitled to vote thereon is sufficient to authorize, affirm, ratify or consent to such act or action, except as otherwise provided by law.

Dividend Rights

Subject to the rights of holders of outstanding shares of preferred stock, if any, holders of Common Stock are entitled to receive such dividends and distributions and other distributions in cash, stock or property of the Company when, as and if declared thereon by the board of directors from time to time out of assets or funds of the Company legally available therefor.

Liquidation Rights

Subject to the rights of holders of outstanding shares of preferred stock, if any, upon our liquidation, dissolution or winding up, the holders of our Common Stock will be entitled to share ratably in the net assets and funds legally available for distribution to stockholders after the payment of all of our debts and other liabilities.

Other Rights and Preferences

Holders of our Common Stock have no preemptive rights or other subscription rights, conversion rights, registration rights, redemption or sinking fund provisions by virtue of only holding such shares.

Anti-Takeover Provisions

Provisions of the DGCL, our Charter, and our Bylaws could make it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions, summarized below, are expected to discourage certain types of coercive takeover practices and takeover bids that our board of directors may consider inadequate and to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because, among other things, negotiation of these proposals could result in improved terms for our stockholders.

Section 203 of the DGCL. We are subject to Section 203 of the DGCL, which generally prohibits a publicly held Delaware corporation from engaging in any "business combination" with any interested stockholder for a period of three (3) years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 of the DGCL defines a "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 of the DGCL defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three (3) years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Anti-Takeover Effects of Certain Provisions of our Charter and Bylaws

Our Bylaws provide that directors may be removed by the stockholders with or without cause upon the vote of a majority of the holders of Common Stock then entitled to vote. Except as otherwise provided in our Bylaws and our Charter, any vacancies or newly created directorships on our board of directors resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director.

Our Bylaws also provide that only our chairman of the board of directors, chief executive officer, president or one or more stockholders holding shares in the aggregate entitled to cast not less than ten percent of the votes at that meeting may call a special meeting of stockholders.

The combination of these provisions makes it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our Common Stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure the Company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Listing

Our Common Stock is listed on the NYSE American LLC under the symbol “CHRO”.

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is Nevada Agency and Transfer Company. The transfer agent’s address is 50 West Liberty Street, Suite 880, Reno NV 89501 and its telephone number is (775) 322-0626.

Exhibit 19.1

CHROMOCELL THERAPEUTICS CORPORATION

Insider Trading Policy

For Employees, Officers and Directors

1. Introduction, Scope and Purpose of Policy

In an effort to protect against prohibited "insider trading" by Chromocell Therapeutics Corporation (the " **Company**") personnel, the Company's Board of Directors (the "**Board**") has adopted this insider trading policy (this " **Policy**") applicable to directors, officers, employees, independent contractors and consultants, whether they work for the Company on a full-time, part-time, consulting, or temporary basis (for the purpose of this Policy, collectively, "**associates**") of the Company and its subsidiaries, Section 16 Individuals (defined below), as well as certain additional persons enumerated herein. The purpose of this Policy is to state the Company's requirement that all associates of the Company and its subsidiaries (and other persons subject to this Policy) comply fully with the laws prohibiting insider trading and tipping and to promote compliance with such laws. Questions regarding this Policy should be directed to the Chief Financial Officer. Violation of the laws prohibiting insider trading and tipping could result in substantial criminal and civil penalties, including (1) imprisonment for up to 20 years, (2) criminal fines of up to $5 million for individuals, and (3) civil penalties of up to the greater of $1 million and three times the profit gained, or loss avoided, so please take time to read and understand the provisions below.

2. Definitions

(A) 10b5-1 Plans. 10b5-1 Plans are contracts, instructions, or plans intended to satisfy the conditions of Rule 10b5-1(c) under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**").

(B) Insider. For purposes of this Policy, the term " **Insider**" refers to any person who, in the course of their employment or as a result of their relationship with the Company, is expected to regularly come into possession, or does come into possession, of material nonpublic information ("**MNPI**") about the Company or its securities and/or of other entities. Therefore, in the case of the Company, directors and officers will be considered Insiders, as will other associates as well as independent contractors, auditors, consultants, attorneys, and other individuals who come into possession of such MNPI. A person may retain his or her Insider status even after leaving the Company.

(C) Key Employees. Key Employees includes the president, each of the Chief Executive Officer, Chief Financial Officer, Chief Strategic Officer, Chief Medical / Scientific Officer, Executive Vice President, Senior Vice President or Vice President, Controller, executive support staff who work for any of the above-named officers, and any other person whose position or responsibilities place them in a position to know quarterly or annual financial results of the Company prior to public announcement.

(D) Material information. Information is generally deemed material if a reasonable investor would consider such information important in making the decision to buy, sell, or hold a security to which the information relates; information reasonably likely to affect the price of a security will generally be material. Material information can be positive or negative and can relate to any aspect of the Company's business or any type of Company security, whether debt, equity, or hybrid. It is not possible to define all categories of material information. While materiality is always a facts and circumstances determination, there are various categories of information that are particularly sensitive and, as a general rule, should always be considered material. Examples of such information are:

- Financial results or projections;
- Major events regarding the Company's securities, including the declaration of stock splits or stock dividends, calls, redemptions, repurchases, dividends, changes in dividend policy, or the possibility of a public or private offering of securities;
- The possibility of mergers, acquisitions, joint ventures, tender offers, or takeovers, the possible initiation of a proxy fight, and similar business developments;
- Significant changes in corporate objectives, operations, business plans, or strategy, or a restructuring;
- A significant cybersecurity incident, such as a data breach, or any other significant disruption in the Company's operations or loss, potential loss, breach, or unauthorized access of its property or assets, whether at its facilities or through its information technology infrastructure;
- Development of a significant new drug candidate, product or service;
- Execution or termination of significant agreements with suppliers, customers, and other business partners;
- Significant related party transactions;
- A purchase or sale by the Company or any subsidiaries of the Company's securities, including a proposed public offering;
- Defaults under agreements or actions by creditors, customers, or suppliers relating to a company's credit standing;
- Major changes in previously-disclosed financial information;
- Changes in debt ratings;
- Unusual borrowings, changes in liquidity or new debt offerings;
- A change in auditors or notification that the auditor's reports may no longer be relied upon;
- The disposition of a subsidiary or of material assets;
- Significant or material legal exposure due to actual, pending or threatened litigation;
- Significant developments in legal proceedings or regulatory actions;

- Significant changes in management or relations among major shareholders (including a change in control), customers, or suppliers; and

- Impending bankruptcy or financial liquidity problems.

The above list is only illustrative; many other types of information may be considered "material," depending on the circumstances, and questions concerning the materiality of particular information should be resolved in favor of materiality, meaning securities transactions should be avoided.

(E) Nonpublic information. Information is "nonpublic" if it has not been previously disclosed to the general public. In order for information to be considered public, it must be widely disseminated in a manner making it generally available to investors, including in a report or other document filed with the U.S. Securities and Exchange Commission (the "**SEC**") through its EDGAR website or through an established media outlet such as Dow Jones, Returns Economic Services, The Wall Street Journal, or The Associated Press; disclosure even to large groups of investors or analysts would not constitute public disclosure, and disclosure solely on the Company's website may not constitute public disclosure. The circulation of rumors, even if accurate and reported in the media, does not constitute effective public disclosure. In addition, even after a public announcement of material information, information will not be considered public until a sufficient time period has elapsed for the disclosed information to be absorbed by the market. **Generally, information should not be considered public until at least two full trading days following the publication or release of such information.**

(F) Related Person. For purposes of this Policy, a Related Person includes: (1) your spouse, children, and anyone else living in your household and persons who do not live in your household but whose transactions in Company securities are directed by you or are subject to your influence or control, such as parents or adult children who consult with you before they trade in Company securities; (2) partnerships in which you are a general partner or corporations in which you are a controlling shareholder; (3) trusts of which you are a trustee; (4) estates in which you are an executor; and (5) any other entities that you control. This Policy applies to your Related Persons to the same extent that it applies to you, and therefore you should make them aware of their need to comply with this Policy and to confer with you before they trade in Company securities, and you should treat all such transactions for the purposes of this Policy and applicable securities laws as if the transactions were for your own account. This Policy does not, however, apply to personal securities transactions of persons or entities who would otherwise fall within the definition of Related Person where the purchase or sale decision is made by a third party not controlled by, influenced by, or related to you or your Related Persons.

(G) Securities Transactions. "**Securities transactions**" subject to this Policy include, among other things, open-market purchases and sales, gifts (other than gifts to Related Persons as such persons are subject to the restrictions of this Policy), placing a purchase or sell order, transactions in a 401(k) account or changes in 401(k) account allocation elections or contributions, and the sale of securities acquired upon the exercise of options or similar instruments. "**Securities**" refers not only to common stock but to all securities of the Company or other applicable entity, including but not limited to bonds, debentures, options, warrants, and partnership or limited liability company interests.

(H) Section 16 Individuals. Each member of the Board, any person owning more than 10% of any registered class of the Company's equity securities (a "10% holder") , those officers of the Company designated by the Board to be "Section 16 Reporting Officers," including but not limited to the Company's chief executive officer; chief financial officer; controller; vice-president(s) in charge of a principal business unit, division or function, or; any other officer who performs a significant policy-making function and any other person who performs similar policy-making functions for the Company, and their respective family members and others in their households, are subject to the reporting provisions and trading restrictions of Section 16 of the Exchange Act and the underlying rules and regulations promulgated by the SEC (the "**Section 16 Individuals**"). Section 16 Individuals must obtain prior approval of all trades in Company securities from the Chief Financial Officer in accordance with the procedures set forth below in Section 3, and may not trade during any Blackout Period (as defined below in Sections 3(C) and 3(D)). For the avoidance of doubt, the pre-approval procedures and prohibitions on trading during any Blackout Period may apply to other personnel, such as Insiders, Key Employees or others, as set forth herein.

3. Guidelines

(A) Non-disclosure of MNPI. Insiders must maintain the confidentiality of any MNPI about the Company or about other entities (including information about transactions being considered by the Company that involve other entities) obtained while carrying out their duties to the Company. You may not disclose such information to anyone, except the persons within the Company or third-party agents of the Company (such as investment banking advisors, outside legal counsel, or outside accountants) whose positions require them to know it, until such information has been publicly disclosed. If any MNPI is inadvertently disclosed, the facts of such disclosure should be immediately reported to the Chief Financial Officer.

(B) Prohibited Trading in Company Securities. Insiders may not engage in transactions in Company securities (nor recommend that another person or entity do so), either directly or through a Related Person or any other person or entity, while in possession of MNPI about the Company or its securities.

(C) Quarterly Trading Restrictions ("Blackout" Periods). Insiders and Section 16 Individuals may not engage in securities transactions in Company securities (either directly or indirectly) or recommend that others do so during the period beginning 10 business days before the end of a fiscal quarter and ending two full business days after the public release of the Company's quarterly (or in the case of the fourth fiscal quarter, quarterly and annual) earnings results.

(D) Additional Blackout Periods. In addition to the quarterly blackout period set forth in Section 3(C) above, the Company may also impose from time to time temporary blackout periods prohibiting all transactions in Company securities by all or certain Insiders and Section 16 Individuals, including in instances when items of significant importance have been communicated to associates prior to its public disclosure. These temporary blackout periods can extend into, and remain in place beyond, the Company's normal recurring quarterly blackout period. The Company will notify you if you are subject to a blackout period. You must not communicate the imposition of a temporary blackout to any other person.

(E) No Trading or Establishing Rule 10b5-1 Plans without Pre-Approval . Key Employees and Section 16 Individuals are required to receive approval from the Chief Financial Officer before buying or selling Company securities (or otherwise making any transfer, gift, pledge or loan thereof). In addition, Key Employees and Section 16 Individuals (other than 10% holders) are required to receive approval from the Chief Financial Officer prior to establishing a 10b5-1 Plan. 10% holders are required to notify the Company before entering into any 10b5-1 Plan. The Chief Financial Officer is required to receive approval related to 10b5-1 Plans from the Chief Executive Officer. Pre-approval may be requested by submitting the "Request for Prior Approval of Stock Trading" (see Exhibit A attached to this Policy) to the Chief Financial Officer. The approval will be evidenced by a countersigned certification. If a Key Employee or Section 16 Individual does not trade within seven calendar days of receiving the countersigned certification, such Key Employee or Section 16 Individual must re-sign and re-submit the pre-approval request. Pre- approval is not required for purchases and sales of stock under an approved 10b5-1 Plan described in Section 3(F) below.

(F) Trading via 10b5-1 Plans.

The Chief Financial Officer requires that each 10b5-1 Plan entered into by a director or Key Employee (including any Section 16 Reporting Officer) include a representation from the individuals adopting the 10b5-1 Plan that such individual (i) is not aware of any MNPI about the Company or its subsidiaries or the Company securities and (ii) is adopting the 10b5-1 Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5 under the Exchange Act.

Additionally, any 10b5-1 Plan will be subject to a "cooling off period" as described below.

(a) Each 10b5-1 Plan adopted by a director or Section 16 Reporting Officer must provide that trading under the 10b5-1 Plan cannot begin until the later of (i) 90 days after the adoption of the 10b5-1 Plan or (ii) two business days following the disclosure of Company's financial results in a 10-Q or 10-K for the fiscal quarter in which the 10b5-1 Plan is adopted (but, in either case, not to exceed 120 days following the adoption of the 10b5-1 Plan).

(b) Each 10b5-1 Plan adopted by a Related Person other than a director or Section 16 Reporting Officer must provide that trading under such 10b5-1 Plan cannot begin until at least 30 days after the adoption of such 10b5-1 Plan.

(c) Any change to the amount, price, or timing of the purchase or sale of Company securities underlying a 10b5-1 Plan constitutes termination of the 10b5-1 Plan and the adoption of a new 10b5-1 Plan, which triggers the "cooling-off" period described above.

(G) Tipping. Insiders may be liable for, and are prohibited from, communicating or "tipping" MNPI to any third party (a "tippee"). A person may qualify as a tippee even if he or she is not a Related Person. Insider trading violations are not limited to the disclosure of MNPI or the use of such information by Insiders. Persons other than Insiders, including tippees, may be liable for insider trading if they trade or take other action based on MNPI that has been misappropriated.

(H) Certain Transactions. To avoid the appearance of impropriety or inadvertent violations of insider trading restrictions, Insiders (and, where indicated, associates generally) may not engage in the types of transactions set forth below:

(a) *Short Sales.* Short sales of Company securities (i.e., the sale of shares of Company common stock that the seller does not own) may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance. For these reasons, short sales of Company securities by directors, officers, and associates are prohibited.

(b) *Publicly-Traded Options.* Given the relatively short term of publicly-traded options, transactions in options may create the appearance that a director, officer, or associate is trading based on MNPI and focus a director's, officer's, or other associate's attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in put options, call options, or other derivative securities, on an exchange or in any other organized market, by directors, officers, and associates are prohibited.

(c) *Hedging Transactions.* Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars, and exchange funds. Such transactions may permit a director, officer, or associate to continue to own Company securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the director, officer, or associate may no longer have the same objectives as the Company's other shareholders. Therefore, directors, officers, and associates are prohibited from engaging in any such transactions.

(d) *Margin Accounts and Pledges.* Securities held in margin accounts or pledged as collateral may be sold by the broker or lender without the account holder or debtor's consent if he or she fails to meet a margin call or defaults on the loan. Because a margin or foreclosure sale could occur at a time when the holder/debtor is aware of MNPI or otherwise is not permitted to trade in Company securities, Insiders are prohibited from holding Company securities in a margin account or otherwise pledging Company securities as collateral for a loan.

(e) *Standing and Limit Orders.* Standing and limit orders create heightened risks for insider trading violations due to the lack of control over the timing of purchases or sales that result from standing instructions to a broker because the broker could execute a transaction when the Insider is in possession of MNPI about the Company. Therefore, Insiders are prohibited from placing standing or limit orders on Company securities.

(f) *No Short-term Trading*. If a Related Person purchases or sells Company securities, such Related Person may not conduct an opposite way transaction in any Company securities of the same class for at least six (6) months after the purchase or sale.

(I) Trading in Other Securities. Insiders may not engage in transactions in the securities of another entity (nor recommend that another person or entity do so), either directly or through a Related Person or any other person or entity, while in possession of MNPI about the other entity or its securities obtained through his or her position at or the carrying out of his or her duties to the Company, as the authorities view that as "shadow trading" (as defined below) the MNPI and therefore may hold Insiders liable for insider trading based on that action.

"Shadow trading" is an emerging theory under the federal securities laws. The SEC has recently alleged that an employee of one company misappropriated MNPI concerning its employer and then committed insider trading by purchasing options in a close competitor of the employer. Although the MNPI did not relate to the close competitor, the employee anticipated that the competitor's stock price would materially increase on the news of its employer's acquisition and that the MNPI was material to the competitor. To that end, the Company forbids any employee from trading in the securities of any company in the Company's industry segment without the pre-clearance or pre-approval of the Chief Financial Officer while in possession of MNPI about the Company, its subsidiaries or Company securities. Absent such approval, employees may not trade in the Company's industry segment. This is because confidential information about one company can be material to other companies, and insider trading liability might attach even when the information at issue is not directly related to the Company.

(J) Prohibitions and Restrictions on 10b5-1 Plans. Subject to the exceptions described in Section 3(K), the following prohibitions and restrictions apply to any Related Person who has adopted a 10b5-1 Plan:

(a) *No Overlapping Plans*. No Related Person may have more than one 10b5-1 Plan for purchases or sales of Company securities on the open market during the same period; provided, however, that a series of separate contracts with different broker-dealers or other agents acting on behalf of such Related Person may be treated as a single 10b5-1 Plan if all such contracts, when taken together as a whole, satisfy all the applicable conditions of, remain subject to, Rule 10b5-1(c)(1) under the Exchange Act; and

(b) *Restrictions on Single-Trade Plans*. No Related Person may have more than one single-trade 10b5-1 Plan during any 12-month period. A single-trade plan is one that has the practical effect of requiring the purchase or sale of Company securities as a single transaction.

(c) *Entry Into and Modifications of 10b5-1 Plans*. Subject to Section 3(F), no Key Employee may enter into, modify or terminate a 10b5-1 Plan during a blackout period, unless otherwise approved by the Chief Financial Officer.

(K) Exceptions.

(a) *General Exceptions*. The restrictions set forth in Sections 3(B), (C), (D), (E), (I) and (J) do not apply to the exercise of stock options for cash under any Company equity compensation plan as the other party to the transaction is the Company itself and the price is fixed by the terms of the option agreement or the plan (but note that such requirements do apply to any sale of stock acquired by exercising any such option, including any such sale as part of a broker-assisted cashless exercise of an option or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option). Similarly, such limitations do not apply to the sale of shares of Company common stock to the Company pursuant to any stock repurchase program approved by the Board.

(b) *10b5-1 Trading Plans*. (i) With respect to overlapping 10b5-1 Plans, a Related Person may have two separate 10b5-1 Plans provided (i) there is no overlap in timing of trades between the two plans, and trading under the earlier-commencing plan concludes or expires before trading is authorized under the later-commencing plan, and (ii) the separate 10b5-1 Plans satisfy all other conditions applicable to 10b5-1 Plans. (ii) With respect to overlapping 10b5-1 Plans, a Related Person may have separate 10b5-1 Plans for "sell-to-cover" transactions in which a Related Person instructs an agent to sell Company securities in order to satisfy tax withholding obligations at the time an equity award vests. Any such additional 10b5-1 Plan must only authorize qualified "sell-to-cover" transactions. (iii) With respect to single-trade 10b5-1 Plans, a Related Person may have a single-trade 10b5-1 Plan for "sell-to-cover" transactions.

(c) *Gifts*. This Policy does not apply to bona fide gifts of Company securities. Related Persons should consider the appearance of any gift viewed in hindsight. Key Employees and Section 16 Individuals: (i) are required to obtain pre-approval from the Chief Financial Officer for gifts of Company securities, and (ii) if Company securities are transferred to a trust formed for estate-planning purposes or a family limited partnership, charitable foundation or similar entity and the director or Key Employee controls the investment and voting decisions of the trust or entity, the director or Key Employee has to confirm in writing that he/she will not permit the trust or entity to trade Securities during a blackout period or otherwise in violation of this Policy.

4. Reporting Requirements

This Policy prohibits short-term trading as described in Section 3(H). U.S. federal securities laws impose additional restrictions on short-term trading. As such, Section 16 Individuals are subject to short-swing profit recovery provisions under U.S. federal securities laws, and Section 16 Individuals must report changes in their beneficial ownership of Company securities with the SEC. The Company will generally assist with the filings required under Section 16 of the Exchange Act on behalf of such Section 16 Individuals. Any Section 16 Individuals who does not hold Company securities through the Company's stock administrator, if any, in addition to having the transaction pre-approved as required herein, must, no later than upon execution, report to the Chief Financial Officer the details of every transaction involving Company securities in which such person engages.

5. Individual Responsibility

Insiders and Section 16 Individuals have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in Company securities while in possession of MNPI. Persons subject to this Policy must not engage in illegal trading and must avoid the appearance of improper trading. Each individual is responsible for making sure that he or she complies with this Policy and that any Related Person also complies with this Policy. In all cases, the responsibility for determining whether an individual is in possession of MNPI rests with that individual, and any action on the part of the Company or any associate or director of the Company pursuant to this Policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws.

In addition, Key Employees and Section 16 Individuals should keep in mind other requirements applicable to the sale of Company securities by them, in particular, compliance with Rule 144 promulgated under, or Section 4(a)(7) of, the Securities Act of 1933, as amended, and be prepared to comply with such requirements in connection with any transactions in Company securities.

If you have any questions regarding this Policy or whether you possess MNPI, it is always advisable to consult with the Chief Financial Officer prior to engaging in any securities transaction.

Adopted on February 14, 2024, subject to the effectiveness of the Company's Registration Statement on Form S-1 for its initial public offering.

EXHIBIT A

CHROMOCELL THERAPEUTICS CORPORATION

PRE-CLEARANCE CERTIFICATION

This Certification is to be submitted by any "Insider" before initiating any transactions in Chromocell Therapeutics Corporation (the "Company") securities. An "Insider" is defined in the Company's Insider Trading Policy.

CERTIFICATION

I certify that:

1. I have read and understand the Chromocell Therapeutics Corporation Insider Trading Policy (the "Policy"). I understand that the Company's Chief Financial Officer is available to answer any questions I have regarding the Policy.

2. I hereby certify that I am not in possession of any "material, non-public information" concerning the Company, as described in the Company's Insider Trading Policy.

3. I understand that, if I trade while possessing such information, I may be subject to severe civil and/or criminal penalties, and may be subject to discipline by the Company including termination. I also acknowledge and understand that I am not permitted to trade until an authorized approval signature is provided below.

Requester signature _____ Date _____

Authorized approval signature _____ Date _____

***Note**: This form is not required in the case of (a) the exercise of stock options acquired under a Company equity compensation plan if the exercise price is paid by the option holder in cash and no shares are sold in the market, (b) a person's election to direct the Company to withhold shares that are subject to an option in order to meet tax withholding requirements provided no shares are sold in the market, (c) the vesting of equity awards or an election to have the Company withhold shares to fulfill tax withholding requirements when the stock vests or (d) gifts made during open window periods. This form is required in the case of a cashless broker-assisted sale of stock and other market sales designed to generate cash to satisfy an option's exercise price or to satisfy tax withholding obligations on the vesting of restricted stock or restricted stock units.*

*Signed certifications should be submitted to the Chief Financial Officer at frank@chromocell.com.

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Chromocell Therapeutics Corporation on Form S-8 (File No. 333-278674) of our report dated April 16, 2024, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the financial statements of Chromocell Therapeutics Corporation as of December 31, 2023 and 2022, and for the years ended December 31, 2023 and 2022, which report is included in this Annual Report on Form 10-K of Chromocell Therapeutics Corporation for the year ended December 31, 2023.

Our report on the financial statements includes an emphasis of matter paragraph as to the preparation of the financial statements on a carve-out basis.

/s/ Marcum LLP

Marcum LLP
Houston, Texas
April 16, 2024

Exhibit 31.1

CERTIFICATION
OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Francis Knuettel II, certify that:

1. I have reviewed this annual report on Form 10-K of Chromocell Therapeutics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 16, 2024

By: /s/ Francis Knuettel II
Francis Knuettel II
Chief Executive Officer

Exhibit 31.2

CERTIFICATION
OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Francis Knuettel II, certify that:

1. I have reviewed this annual report on Form 10-K of Chromocell Therapeutics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April; 16, 2024

By: /s/ Francis Knuettel II
Francis Knuettel II
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION
OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF
THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Chromocell Therapeutics Corporation (the "Company") on Form 10-K for the period ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Francis Knuettel II, Chief Executive Officer of Chromocell Therapeutics Corporation, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and
(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 16, 2024

By: /s/ Francis Knuettel II
Francis Knuettel II
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION
OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF
THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Chromocell Therapeutics Corporation (the "Company") on Form 10-K for the period ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Francis Knuettel II, Chief Financial Officer of Chromocell Therapeutics Corporation, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and
(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 16, 2024

By: /s/ Francis Knuettel II
Francis Knuettel II
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 97.1

CHROMOCELL THERAPEUTICS CORPORATION

CLAWBACK POLICY

Effective as of February 14, 2024

Background

The Board of Directors (the "**Board**") of Chromocell Therapeutics Corporation (the "**Company**") believes that it is in the best interests of the Company and its stockholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company's pay-for-performance compensation philosophy. The Compensation Committee of the Board (the "**Compensation Committee**") and the Board have therefore adopted this policy, which provides for the recoupment (or clawback) of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws of the United States (the "**Policy**"). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), Rule 10D-1 promulgated under the Exchange Act ("**Rule 10D-1**") and the listing standards of the NYSE American LLC (" **NYSE American**") under Section 811 of the NYSE American Company Guide (the "Company Guide").

Administration

This Policy shall be administered by the Compensation Committee. Any determinations made by the Compensation Committee shall be final and binding on all affected individuals. Subject to any limitation under applicable law, the Compensation Committee may authorize and empower any officer or employee of the Company to take any and all actions necessary or appropriate to carry out the purpose and intent of this Policy (the "**Authorized Officers**") (other than with respect to any recovery under this Policy involving such officer or employee).

Covered Executives

This Policy applies to the Company's current and former executive officers, as determined by the Board in accordance with Section 10D of the Exchange Act and the listing standards of NYSE American ("**Covered Executives**").

Recoupment; Accounting Restatement

In the event the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, the Compensation Committee will require prompt reimbursement or forfeiture of any excess Incentive Compensation (as defined below) received by any Covered Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare an accounting restatement. For the sake of clarity, recoupment is required in the event of any restatement that either: (a) corrects an error in previously issued financial statements that is material to the previously issued financial statements; or (b) corrects an error not material to previously issued financial statements, but that would result in a material misstatement if (i) the error was left uncorrected in the then current period; or (ii) the error correction was recognized in the then current period. The Company's obligation to recover erroneously awarded compensation is not dependent on if or when the restated financial statements are filed. For purposes of determining the relevant recovery period, the date that the Company is required to prepare an accounting restatement as described above is the earlier to occur of: (A) the date the Board, a committee of the Board, the Authorized Officers, or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement as described above; or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare an accounting restatement as described above. In accordance with Section 811 of the Company Guide, this Policy is applicable to Incentive Compensation (as described below) received on or after October 2, 2023.

Incentive Compensation

For purposes of this Policy, "Incentive Compensation" means any of the following, provided that such compensation is granted, earned or vested based wholly or in part on the attainment of a financial reporting measure affected by the restated financial statements:

- Annual bonuses and other short- and long-term cash incentives.
- Stock options.
- Stock appreciation rights.
- Restricted stock.
- Restricted stock units.
- Performance shares.
- Performance units.

Financial reporting measures are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total stockholder return are also financial reporting measures. A financial reporting measure need not be presented within the financial statements or included in a filing with the Securities and Exchange Commission. The Company's financial reporting measures may include, but are not limited to, the following:

- Company stock price.
- Total stockholder return.
- Revenues.
- Net income.
- Earnings before interest, taxes, depreciation and amortization (EBITDA).
- Funds from operations.
- Liquidity measures such as working capital, operating cash flow or Free Cash Flow.
- Return measures such as return on invested capital or return on assets.
- Earnings measures such as earnings per share.

This Policy applies to all Incentive Compensation received by a Covered Executive:

- After beginning service as an executive officer;
- Who served as an executive officer at any time during the performance period for that Incentive Compensation;
- While the Company has a class of securities listed on a national securities exchange or a national securities association; and
- During the three completed fiscal years immediately preceding the date that the Company is required to prepare an accounting restatement as described in this Policy. In addition to these last three completed fiscal years, this Policy applies to any transition period (that results from a change in the Company's fiscal year) within or immediately following those three completed fiscal years. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months would be deemed a completed fiscal year.

Incentive Compensation is deemed received in the Company's fiscal period during which the financial reporting measure specified in the Incentive Compensation award is attained, even if the payment or grant of the Incentive Compensation occurs after the end of that period.

Excess Incentive Compensation: Amount Subject to Recovery

The amount to be recovered will be the excess of the Incentive Compensation paid to the Covered Executive based on the erroneous data over the Incentive Compensation that would have been paid to the Covered Executive had it been based on the restated results, as determined by the Compensation Committee, and without regard to any taxes paid by or withheld from the Covered Executive. If the Compensation Committee cannot determine the amount of excess Incentive Compensation received by the Covered Executive directly from the information in the accounting restatement, then it will make its determination based on a reasonable estimate of the effect of the accounting restatement. For Incentive Compensation based on stock price or total stockholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement, the amount will be based on a reasonable estimate of the effect of the accounting restatement on the stock price or total stockholder return upon which the Incentive Compensation was received. In such case, the Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to NYSE American.

Method of Recoupment

The Compensation Committee will determine, in its sole discretion, the method for recouping Incentive Compensation hereunder which may include, without limitation:

- Requiring reimbursement of cash Incentive Compensation previously paid;
- Seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
- Offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive in accordance with applicable law;
- Cancelling outstanding vested or unvested equity awards; and/or
- Taking any other remedial and recovery action permitted by law, as determined by the Compensation Committee.

No Indemnification

The Company shall not indemnify any Covered Executives against the loss of any Incentive Compensation recovered under this Policy or from any consequence arising therefrom.

Interpretation

The Compensation Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act, Rule 10D-1 and any applicable rules or standards adopted by the Securities and Exchange Commission or NYSE American.

Effective Date

This Policy shall be effective as of the date it is adopted by the Board (the " **Effective Date**") and, in accordance with Section 811 of the Company Guide, shall apply to Incentive Compensation that is received by Covered Executives on or after October 2, 2023.

Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect regulations adopted by the Securities and Exchange Commission under Section 10D of the Exchange Act and to comply with any rules or standards adopted by NYSE American. The Board may terminate this Policy at any time.

Other Recoupment Rights

The Board intends that this Policy will be applied to the fullest extent of applicable law. The Board or Compensation Committee may require that any employment agreement, equity award agreement, or similar agreement entered into or amended on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of: (a) any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement or similar agreement and any other legal remedies available to the Company, including termination of employment or institution of legal proceedings; and (b) any statutory recoupment requirement, including Section 304 of the Sarbanes-Oxley Act of 2022. For the avoidance of doubt, any amounts paid to the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2022 shall be considered (and may be credited) in determining any amounts recovered under this Policy.

Impracticability

The Compensation Committee shall recover any excess Incentive Compensation in accordance with this Policy unless such recovery would be impracticable, as determined in accordance with Rule 10D-1(b)(1)(iv) under the Exchange Act and the listing standards of NYSE American. In order for the Company to determine that recovery would be impracticable, the Company's Compensation Committee must conclude the following:

a) The direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered after making a reasonable attempt to recover such Incentive Compensation. Note that the attempt(s) to recover must be documented by the Company and such documentation provided to NYSE American;

b) Recovery would violate home country law where that law was adopted prior to November 28, 2022. Note that the Company must obtain a legal opinion of home country counsel that such recovery would result in a violation of local law and provide such opinion to NYSE American; or

c) Recovery would likely cause an otherwise tax-qualified retirement plan under which benefits are broadly available to Company employees to fail to meet the requirements for qualified pension, profit-sharing and stock bonus plans under Section 401(a)(13) of the U.S. Internal Revenue Code or the minimum vesting standards under Section 411(a) of the U.S. Internal Revenue Code.

Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

Exhibit Filing

A copy of this Policy shall be filed as an exhibit to the Company's annual report on Form 10-K.

ATTESTATION AND ACKNOWLEDGEMENT OF CLAWBACK POLICY FOR CHROMOCELL THERAPEUTICS CORPORATION

By my signature below, I acknowledge and agree that:

- I have received and read the attached Clawback Policy (the "Policy") of Chromocell Therapeutics Corporation (the " **Company**").
- I hereby agree to abide by all of the terms of the Policy both during and after my employment with the Company, including, without limitation, by promptly repaying or returning any incorrectly awarded Incentive Compensation to the Company as determined in accordance with the Policy.
- I hereby waive any claim against the Company, its Authorized Officers and the Board in connection with the implementation of the Policy.

Signature: _____

Printed Name: _____

Date: _____